

Risk Assessment for Use of Imidacloprid to Control Burrowing Shrimp in Shellfish Beds of Willapa Bay and Grays Harbor, WA

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Table of Contents

| | |
|---|----|
| Executive Summary | 7 |
| 1. Introduction | 9 |
| 1.1 Site descriptions and proposed use | 9 |
| 1.2 Objective..... | 9 |
| 1.3 Information sources | 10 |
| 2. Problem formulation | 10 |
| 2.1 Nature of imidacloprid as a stressor | 10 |
| 2.2 Ecological receptors that may be exposed to imidacloprid use | 10 |
| 2.3 Considerations of human exposure..... | 10 |
| 3. Label Description and History | 11 |
| 3.1 Registration status..... | 11 |
| 3.2 Proposed use pattern, current labels, and Material Safety Data Sheets | 11 |
| 3.3 Additional comments on efficacy and extent of use | 12 |
| 4. Chemical Characteristics | 12 |
| 4.1 Composition of the imidacloprid end use products | 13 |
| 4.1.1 Active ingredients | 13 |
| 4.1.2 Impurities | 13 |
| 4.1.3 Added inert ingredients..... | 14 |
| 4.1.4 Added synergists | 14 |
| 4.1.5 Nature of formulation (e.g., powder, emulsifiable concentrate) | 14 |
| 4.2 Color | 15 |
| 4.3 Physical state | 15 |
| 4.4 Odor | 15 |
| 4.5 Melting point | 15 |
| 4.6 Boiling point..... | 15 |
| 4.7 Density, bulk density or specific gravity | 16 |
| 4.8 Solubility | 16 |
| 4.9 Vapor pressure..... | 16 |
| 4.10 Disassociation constant..... | 16 |
| 4.11 Octanol/water partition coefficient | 17 |
| 4.12 pH | 17 |
| 4.13 Stability..... | 17 |
| 4.14 Oxidizing or reducing action | 17 |
| 4.15 Flammability..... | 17 |
| 4.16 Explodability | 18 |
| 4.17 Storage stability | 18 |
| 4.18 Viscosity | 18 |
| 4.19 Miscibility..... | 18 |
| 4.20 Corrosion characteristics | 18 |
| 4.21 Dielectric breakdown voltage | 18 |
| 5. Environmental Fate..... | 19 |
| 5.1 Volatilization | 19 |
| 5.2 Hydrolysis..... | 19 |
| 5.2.1 Half-life..... | 19 |
| 5.2.2 Degradation products | 19 |
| 5.3 Aqueous photolysis..... | 19 |
| 5.4 Soil photolysis | 20 |
| 5.5 Degradation and persistence – soil | 21 |
| 5.5.1 Half-life..... | 21 |

| | | |
|--------|---|----|
| 5.5.2 | Degradation products | 21 |
| 5.6 | Degradation and persistence - aquatic systems..... | 22 |
| 5.6.1 | Half-life and disappearance time | 22 |
| 5.6.2 | Degradation products | 23 |
| 5.7 | Microbial degradation..... | 24 |
| 6. | Environmental Effects | 24 |
| 6.1 | Objectives | 24 |
| 6.2 | Mobility | 25 |
| 6.2.1 | Soil | 25 |
| 6.2.2 | Sediment | 25 |
| 6.2.3 | Groundwater | 25 |
| 6.3 | Sources of information | 25 |
| 6.4 | Toxicity information..... | 26 |
| 6.4.1 | Microbes | 26 |
| 6.4.2 | Algae..... | 26 |
| 6.4.3 | Aquatic macrophytes..... | 26 |
| 6.4.4 | Fish..... | 26 |
| 6.4.5 | Aquatic invertebrates | 27 |
| 6.4.6 | Sediment organisms | 29 |
| 6.4.7 | Biological field studies..... | 29 |
| 6.4.8 | Amphibians | 31 |
| 6.4.9 | Toxicity to birds | 32 |
| 6.4.10 | Toxicity to mammals | 32 |
| 6.4.11 | Terrestrial plants | 32 |
| 7. | Ecological Exposure Assessment | 32 |
| 7.1 | Routes of exposure | 32 |
| 7.1.1 | Aquatic plants and algae | 32 |
| 7.1.2 | Fish and other aquatic vertebrates; aquatic invertebrates..... | 33 |
| 7.1.3 | Terrestrial Organisms..... | 33 |
| 7.2 | Concentrations of imidacloprid | 35 |
| 7.2.1 | Water column..... | 36 |
| 7.2.2 | Sediments..... | 37 |
| 7.2.3 | Adjacent terrestrial areas..... | 39 |
| 7.3 | Persistence and duration of residues | 39 |
| 7.3.1 | Water column..... | 39 |
| 7.3.2 | Sediment and pore water..... | 39 |
| 7.3.3 | Peak residues selected for risk assessment..... | 39 |
| 7.4 | Bioconcentration and bioaccumulation | 39 |
| 7.5 | Ground and well water considerations | 40 |
| 7.5.1 | General aspects of groundwater and wells..... | 40 |
| 7.5.2 | Mobility of imidacloprid and considerations for use in fractured basaltic areas | 40 |
| 8. | Risk Assessment and Characterization for Ecological Effects | 40 |
| 8.1 | Effects..... | 40 |
| 8.1.1 | Aquatic organisms..... | 40 |
| 8.1.2 | Terrestrial biota | 43 |
| 8.1.3 | Endangered and Threatened Species..... | 46 |
| 8.2 | Effects on water quality | 57 |
| 8.3 | Effects from interactions with other pesticides..... | 57 |
| 8.4 | Effects on pristine and contaminated sites..... | 57 |
| 8.5 | Indirect effects | 58 |
| 8.6 | Impacts of multiple applications..... | 58 |

| | | |
|--------|---|----|
| 8.7 | Impacts on terrestrial organisms and environments | 58 |
| 8.8 | Impacts on wetlands other than target application sites | 58 |
| 8.9 | Uncertainty analysis | 58 |
| 8.10 | Additional needs for information..... | 58 |
| 8.10.1 | Soil and sediment | 58 |
| 8.10.2 | Water..... | 58 |
| 8.10.3 | Plants..... | 59 |
| 8.10.4 | Acute toxicity studies..... | 59 |
| 8.10.5 | Chronic toxicity studies | 59 |
| 8.11 | Mitigation measures | 59 |
| 9. | Human Health Effects | 59 |
| 9.1 | Objective..... | 59 |
| 9.2 | Information compilation | 60 |
| 9.3 | Toxicology information and assessment | 60 |
| 9.3.1 | Acute..... | 61 |
| 9.3.2 | Pharmacokinetics – absorption, distribution, and metabolism..... | 64 |
| 9.3.3 | Subchronic toxicity | 65 |
| 9.3.4 | Chronic toxicity..... | 67 |
| 9.3.5 | Reproductive and developmental toxicity..... | 68 |
| 9.3.6 | Carcinogenicity and mutagenicity..... | 68 |
| 9.3.7 | Epidemiology | 69 |
| 9.3.8 | Human case reports and studies | 69 |
| 9.4 | Exposure assessment | 69 |
| 9.4.1 | Potential routes of exposure..... | 69 |
| 9.4.2 | Exposure route summary | 74 |
| 10. | Risk Assessment and Characterization for Health Effects | 74 |
| 10.1 | Residential exposure results and characterization | 74 |
| 10.2 | Dietary exposure results and characterization | 74 |
| 10.3 | Applicator exposure results and characterization | 75 |
| 10.4 | Incidental exposure from recreation results and characterization..... | 76 |
| 10.5 | Chronic exposure..... | 76 |
| 10.6 | Uncertainties..... | 76 |
| 10.7 | Conclusions | 76 |

Tables

| | | |
|-------------|--|----|
| Table 4.1. | Color of imidacloprid and formulations..... | 15 |
| Table 4.2 | Physical state of imidacloprid and formulations..... | 15 |
| Table 4.3 | Odor of imidacloprid and formulations | 15 |
| Table 4.4 | Melting point of imidacloprid and formulations..... | 15 |
| Table 4.5. | Bulk density of imidacloprid and formulations | 16 |
| Table 4.6. | Solubility of imidacloprid and formulations..... | 16 |
| Table 4.7. | Vapor pressure of imidacloprid | 16 |
| Table 4.8. | Octanol-water partition coefficient of imidacloprid | 17 |
| Table 4.9. | pH of imidacloprid and formulations..... | 17 |
| Table 4.10. | Flash point of imidacloprid formulations..... | 17 |
| Table 4.11. | Viscosity of imidacloprid and formulations..... | 18 |
| Table 5.1. | Pattern of metabolites in water samples as a function of time (determined by TLC, in % of the radioactivity initially applied)..... | 23 |
| Table 5.2. | Pattern of metabolites as a function of time (determined by TLC, in % of the radioactivity initially applied) for system IJzendoorn (mean from two incubation vessels) | 24 |

| | |
|---|----|
| Table 6.1. Laboratory toxicity studies detailing imidacloprid effects on estuarine/marine fish | 26 |
| Table 6.2. Laboratory toxicity studies on imidacloprid effects on estuarine/marine invertebrates | 27 |
| Table 6.3. Biological observations made after imidacloprid treatments of oyster beds in Willapa Bay and Grays Harbor..... | 30 |
| Table 6.4. Avian toxicity endpoints for imidacloprid..... | 32 |
| Table 6.5. Mammalian toxicity endpoints for imidacloprid | 32 |
| Table 7.2. Proposed focal species for assessing risk to mammals from applications of imidacloprid for control of burrowing shrimp in Grays Harbor and Willapa Bay, WA..... | 35 |
| Table 7.3. Imidacloprid residues in Willapa Bay and Grays Harbor water above treated oyster beds and in nearby water..... | 37 |
| Table 7.4. Imidacloprid residues in Willapa Bay and Grays Harbor sediments and pore water in treated oyster beds and in nearby sites | 38 |
| Table 7.5. Typical maximum imidacloprid residues in field studies in Willapa Bay and Grays Harbor (0.5 lb a.i./acre treatment)..... | 39 |
| Table 8.1. Levels of Concern for pesticide risk (US EPA 2004) | 40 |
| Table 8.2. Acute Risk Quotients (RQs) for imidacloprid using residues from treated oyster beds (on- bed) and surrogate species for Willapa Bay and Grays Harbor. RQs in bold exceed the Level of Concern. | 41 |
| Table 8.3. Acute Risk Quotients (RQs) for imidacloprid using residues from channels adjacent to treated oyster beds (off-bed) and surrogate species for Willapa Bay and Grays Harbor. RQs in bold exceed the Level of Concern. | 42 |
| Table 8.4. Chronic risk quotients (RQs) for imidacloprid using residues from treated oyster beds (on- bed) and available surrogate species data for Willapa Bay and Grays Harbor..... | 42 |
| Table 8.5. Acute risk quotients (RQs) for imidacloprid using residues from treated oyster beds (on- bed) and species located in Willapa Bay and Grays Harbor. RQs in bold exceed the level of concern..... | 43 |
| Table 8.6. Acute risk quotients (RQs) for imidacloprid using residues from channels adjacent to treated oyster beds (off-bed) and species located in Willapa Bay and Grays Harbor. | 43 |
| Table 8.7. Imidacloprid risk estimation for birds. RQ in bold exceeds the level of concern..... | 44 |
| Table 8.8. Imidacloprid risk estimation for mammals | 45 |
| Table 8.9. Listed species and critical habitat occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA | 47 |
| Table 8.10. Summary of diets of the listed fish occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA. | 48 |
| Table 8.12. Summary of conclusions for listed species, indirect effects and critical habitat occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA. | 57 |
| Table 9.1 Summary of Imidacloprid Acute Toxicity Studies | 61 |
| Table 9.2 Acute Toxicity Categories for Imidacloprid | 64 |
| Table 9.3 EPA Acute Toxicity Categories and Signal Words | 64 |
| Table 9.4 Summary of Studies of Imidacloprid Synergism with other Pesticides..... | 65 |
| Table 9.5 Subchronic Oral Toxicity Studies | 66 |
| Table 9.6 Chronic Toxicity Studies | 68 |
| Table 9.7 Summary of Short-term Residential Handler Exposure and Risks | 71 |
| Table 9.8 Exposure Potential for Adult and Child Short-term Aggregate Risk Estimates | 73 |

Figures

| | |
|--|----|
| Figure 5.1. Imidacloprid photolysis products in water. Source: Bacey, 2001. | 20 |
| Figure 5.2. Proposed metabolic pathway for the aerobic degradation in soil of imidacloprid. Source: EFSA 2006. | 22 |

Appendices

| | |
|---|-----|
| APPENDIX A. Mallet 2F Material Safety Data Sheet..... | 85 |
| APPENDIX B. Mallet 0.5G Material Safety Data Sheet..... | 92 |
| APPENDIX C. Protector 2F Formulation Label | 99 |
| APPENDIX D. Protector 0.5G Formulation Label..... | 106 |
| APPENDIX E. Human Health Incident Reports..... | 112 |
| APPENDIX F. Glossary | 128 |

Risk Assessment for Use of Imidacloprid to Control Burrowing Shrimp in Shellfish Beds of Willapa Bay and Grays Harbor, WA

Executive Summary

The potential effects of imidacloprid use for the control of burrowing shrimp in Willapa Bay and Grays Harbor have been studied extensively over the past six years. Studies have included investigations of chemical residues, laboratory and field toxicity using surrogate and local species, and biological field sampling under commercial use conditions. The overriding weight of evidence indicates that imidacloprid treatment will not significantly impact the endemic species or the ecology of these waters, and will not significantly impact human health.

The use of imidacloprid in Willapa Bay and Grays Harbor will be limited in both timing and spatial scope. To reduce the impact of the burrowing shrimp species on shellfish production, these products will be used to treat targeted beds approximately once every 3 - 4 years on a rotating basis (although applications in consecutive years are allowed). Not all shellfish beds require treatment, dependent on the resident population of burrowing shrimp. There are approximately 45,000 acres of tidelands in Willapa Bay, with only 20% used for commercial shellfish (largely oysters and clams). In Grays Harbor, shellfish are grown commercially on only 3% of the 9,000 acres of tideland. These facts indicate that exposure will be significantly limited within the two water bodies.

The Willapa Bay and Grays Harbor systems both experience significant flushing associated with daily tidal patterns, with major daily tidal fluctuations ranging between six and ten feet. This extensive water exchange is necessary for commercial shellfish production and provides several critical inputs into these environments. Tidal flows provide water dilution and movement, increasing opportunities for rapid dissipation of imidacloprid. Tidal changes also bring in water that is rich in nutrients and microorganisms, supporting more rapid metabolic breakdown of chemicals such as imidacloprid. This rapid breakdown and subsequent decline in concentrations is supported in multiple residue studies involving water and sediments associated with treated beds and adjacent channels. Based on these observations, exposures of non-target organisms to biologically active concentrations of imidacloprid would be significantly limited and brief.

Numerous studies have been conducted on the effects of imidacloprid on estuarine and marine organisms. Results indicate that the majority of surrogate and endemic species are not sensitive to environmentally relevant concentrations of imidacloprid. This includes fish, mollusks, polychaetes and some crustaceans. Although there are some indications of toxicity to specific crustaceans, the impact is expected to be minor because of limited exposures and rapid re-colonization.

Biological field trials were conducted on commercially treated oyster beds in Willapa Bay and Grays Harbor. Imidacloprid was found to have a limited impact on certain crustaceans on treated beds, although ecological indices showed minor, transient changes in the fauna on commercial oyster plots. Researchers believe that these data suggest a short-lived toxic effect on the most sensitive macro-invertebrates (primarily crustaceans) followed by a rapid recovery through product dissipation and re-colonization with tidal flushing. The proposed use of imidacloprid to treat burrowing shrimp in shellfish beds located in Willapa Bay and Grays Harbor is expected to have little or no impact on the local estuarine and marine species.

In its 2009 review for the imidacloprid Experimental Use Permit (EUP), the US Environmental Protection Agency (US EPA) stated that “no risks to terrestrial organisms are expected because the proposed uses are all in aquatic areas.” The current ecological risk assessment, using Brant, Heermann’s Gull, Western Snowy Plover, and Raccoon as focal species, confirms that there is minimal acute or chronic risk to birds and mammals from the use of imidacloprid to control burrowing shrimp on shellfish beds in Willapa Bay and Grays Harbor.

Imidacloprid use will have no direct effects on any of the 14 listed (threatened or endangered) species in Willapa Bay and Grays Harbor. There will be no indirect effects on bull trout, Pacific eulachon, northern spotted owl, short-tailed albatross, Oregon checkerspot butterfly, or Columbia white-tailed deer, and imidacloprid is not likely to cause adverse indirect effects on the other listed species. Imidacloprid will not cause habitat modification for bull trout, Pacific eulachon, marbled murrelet, and northern spotted owl, and is not likely to cause adverse habitat modification for any of the other listed species.

The proposed use of imidacloprid is not likely to result in adverse human health effects. Imidacloprid is not considered toxic to humans via dermal or inhalation exposure routes. It is designated an acute oral toxicant, but residues in fish and shellfish are below the detection limit and pose no threat even under conservative aggregate exposure scenarios. The subpopulations most vulnerable to dietary exposure—infants and children—are the least likely to consume high levels of fish and shellfish. This assessment also considered scenarios including population subgroups that are prone to higher levels of fish/shellfish consumption, but these did not alter the conclusions reached in this risk assessment.

Applicators inherently face the possibility of acute exposure, particularly in the event of an accidental dose. The label instructions require that applicators wear protective equipment beyond US EPA Human Effects Division’s (HED’s) more conservative expectations (e.g. applicators of the granular formulation must wear dust masks during application). All of HED’s applicator scenarios resulted in Margins of Exposure (MOEs) “not of concern,” when applicators wore gloves. As the formulation labels restrict usage to a single application per year, there is no risk of chronic or subchronic exposure to handlers or other groups.

The overriding weight of evidence indicates that imidacloprid treatment will not significantly impact endemic species or the ecology of Willapa Bay and Grays Harbor, and will not significantly impact human health.

1. Introduction

In conjunction with an ongoing Washington State University (WSU) research program, the Willapa Bay/Grays Harbor Oyster Growers Association (WGHOGA) has obtained a federal registration for use of imidacloprid to control burrowing shrimp on oyster beds in Willapa Bay and Grays Harbor. Recent US Environmental Protection Agency (US EPA) assessments of imidacloprid provide extensive information on the compound's environmental fate and ecotoxicology. US EPA's November 2009 review of WSU's application for an Experimental Use Permit (EUP) for imidacloprid on Washington State oyster beds (US EPA 2009) concluded that "risks within the Bay will likely be localized to the target area." The current risk assessment addresses commercial use of imidacloprid on shellfish beds in these water bodies. The assessment was prepared by Compliance Services International (CSI), Lakewood, WA, using information from the EUP assessment, US EPA Registration Review documents, WGHOGA, research groups at WSU and other institutions, and the open literature. The assessment is based on the standard process used by US EPA's Office of Pesticide Programs (US EPA 2004), adapted to the special circumstances of the proposed use.

1.1 Site descriptions and proposed use

The use of imidacloprid is proposed to control burrowing shrimp (ghost shrimp, *Neotrypaea californiensis*, and mud shrimp, *Upogebia pugettensis*) on tidal flats that support shellfish (primarily oyster production in Willapa Bay and Grays Harbor in Washington State). Willapa Bay is the largest outer coastal estuary in Washington. At high tide the water covers approximately 88,000 acres (~100 square miles), but water only covers about half of that amount at low tide, revealing extensive tidal mud flats (Cohen et al. 2001). Grays Harbor is about 17 miles (27 km) long and 12 miles (19 km) wide (Gulick 1996), and also has extensive tidal mud flats. Several rivers drain into each of the bays. Of the 45,000 acres of tidelands in Willapa Bay and 34,460 in Grays Harbor, approximately 9,000 acres (20 percent) in Willapa and 900 acres (3 percent) in Grays Harbor are farmed for oysters or clams (WDOE 2006). Additional use on clam beds is not expected to significantly increase total acreage treated. Total acreage is not expected to expand due to land use and shoreline restrictions; furthermore, any additional acreage—if even possible—would likely require permitting or regulatory approval by the U.S. Army Corps of Engineers, and the Washington Department of Ecology (WDOE).

In Willapa Bay, the WDOE estimates that there are 15,000-20,000 acres of tidelands dominated by burrowing shrimp (WDOE 2006). In some areas, burrowing shrimp occur at densities high enough to preclude oyster cultivation. The action of the burrowing shrimp that affects oyster production is that of making sufficient holes underneath the oysters to cause the oysters to sink and suffocate (McGinnis 2008). In addition, high shrimp densities may affect the eelgrass that often covers the tidal flats.

Since the 1960s, carbaryl has been used to control the shrimp. This use is under a Special Local Needs (FIFRA 24c) registration with the Washington State Department of Agriculture. However, carbaryl is being phased out, and imidacloprid has been investigated as a replacement. Based upon preliminary research studies, the use of imidacloprid products Protector 2F (21.4% flowable) and Protector 0.5G (0.5% granular) was proposed for registration, and final labeling was accepted by EPA in June of 2013. The primary site is oyster beds, however, use is also allowed by the approved label on beds with Manila clams and other clams.

1.2 Objective

The objective of this analysis is to provide an ecological and human health risk assessment of imidacloprid to support an application by WGHOGA for a permit to use the imidacloprid end use products Protector 2F and Protector 0.5G on shellfish beds for control of burrowing shrimp.

1.3 Information sources

The ecological portion of this assessment draws heavily upon previous US EPA assessments (US EPA 2008a,b,c, 2009), WGHOGA field studies conducted at both treatment sites, GLP studies of imidacloprid toxicity, and public data on threatened and endangered species. The human health assessment draws primarily from documents developed by the US EPA and the European Food Safety Authority (EFSA) for imidacloprid registration review. The results and discussions from several studies were obtained through US EPA and EFSA reports.

2. Problem formulation

An analysis of the use of imidacloprid on shellfish beds in Washington State first requires a problem formulation such as that described in EPA's Framework for Ecological Risk Assessment (US EPA, 1992), and updated in the Guidelines for Ecological Risk Assessment (US EPA 1998). The problem formulation describes the nature of the stressor (imidacloprid) and potential exposure to ecological and human receptors.

2.1 Nature of imidacloprid as a stressor

Imidacloprid is a member of the neonicotinoid class of pesticide. Like the other neonicotinoids, imidacloprid shares structural similarity and a common mode of action with the tobacco toxin, nicotine (CEPA-DPR, 2006). The toxicity of imidacloprid is based on interference of the neurotransmission in the nicotinic cholinergic nervous system. Imidacloprid binds to the nicotinic acetylcholine receptor (nAChR) at the neuronal and neuromuscular junctions in insects and vertebrates. The nAChR is an ion channel, which endogenous agonist is the excitatory neurotransmitter acetylcholine (ACh). The receptor normally exists in a closed state, however, upon ACh binding, the complex opens a pore and becomes permeable for cations. The channel openings occur in short bursts, which represent the lifetime of the receptor-ligand complex. ACh is then rapidly degraded by the enzyme acetylcholinesterase (AChE). In contrast, imidacloprid bound to the nAChR is inactivated very slowly. Prolonged activation of the nAChR by imidacloprid causes desensitization and blocking of the receptor and leads to paralysis and death (CEPA-DPR, 2006).

2.2 Ecological receptors that may be exposed to imidacloprid use

Aquatic organisms will be exposed to imidacloprid when it is applied. Burrowing shrimp are the intended receptors, but exposure of other aquatic organisms in the treatment area is unavoidable from this use. There is enough information to conclude that toxic effects on aquatic plants are unlikely. This risk assessment is therefore primarily oriented towards aquatic animals.

While potential exposure of terrestrial organisms as a result of spray drift from the Protector 2F formulation cannot be completely ruled out, it is unlikely. Imidacloprid is to be applied directly to sediment beds at low tide. Applications made at ground level, such as from a boat, backpack sprayer, or by drip stations typically have limited amounts of drift. Certain terrestrial animals may ingest imidacloprid residues in aquatic food. Birds, mammals, and reptiles could be exposed through dermal contact while in treated waters. Species exposed frequently, such as piscivorous birds, ducks, muskrats, garter snakes, and others, would be most at risk from the use of imidacloprid. There is no reason to expect that terrestrial plants would be sensitive, even in the unlikely event that they would be exposed.

2.3 Considerations of human exposure

Humans may be exposed to imidacloprid in several ways. The highest potential exposure would be from a combination of dermal exposure from recreational swimming and/or wading, and dietary exposure from

consumption of fish or shellfish from waters overlying either treatment site. Dermal and inhalation exposure would be the primary routes of exposure for applicators. The Protector formulation labels require applicators to post signs informing recreational users that imidacloprid will be applied for burrowing shrimp control on commercial shellfish beds, and warning the public not to fish, crab, or clam within one-quarter mile of the treated area.

3. Label Description and History

3.1 Registration status

US EPA published a summary document for imidacloprid as part of the Registration Review process (US EPA 2008a). The following discussion of the registration status of imidacloprid is drawn from that document.

Imidacloprid is a systemic neonicotinoid insecticide that is used to control soil insects, sucking insects, chewing insects, and termites. It was first registered by US EPA in 1994. Eleven technical registrants hold over 390 Section 3 registrations and over 30 Section 24(c) registrations.

Registered formulations of imidacloprid include dry flowables, dusts, emulsifiable concentrates, soluble concentrates, granulars, impregnated materials, liquids, pellets/tablets, plant spikes, ready to use liquids, water dispersible granules, and wettable powders.

3.2 Proposed use pattern, current labels, and Material Safety Data Sheets

Imidacloprid has both residential and agricultural uses. The residential uses include lawns, turf, golf courses, ornamental plantings, pets, and pre-and post-construction uses as a termiticide and wood preservative. The major agricultural uses include corn, lettuce, broccoli, apples, and potatoes.

The current assessment addresses the proposed use of imidacloprid to control burrowing shrimp (ghost shrimp, *Neotrypaea californiensis*, and mud shrimp, *Upogebia pugettensis*) on tidal flats that support oyster (primarily) and other bivalve production in Willapa Bay and Grays Harbor in Washington State (see Section 1.1).

Based upon preliminary research studies, the use of imidacloprid products Protector 2F (21.4% flowable) and Protector 0.5G (0.5% granular) has shown good efficacy and these formulations are now fully registered by EPA for the uses reviewed in this risk assessment. The primary site is oyster beds, however, use is also allowed by the label on beds with Manila clams and other clams. Copies of the EPA-stamped accepted labels are attached in Appendices C and D.

Both formulations may only be sold to members of the Willapa Grays Harbor Oyster Growers Association (WGHOGA). Application is only allowed for control of burrowing shrimp (*N. californiensis* and *U. pugettensis*), and only in Willapa Bay and Grays Harbor.

The maximum application rate is 0.5 lb active ingredient (a.i.)/acre. There is a maximum of one application per year. Unless there is poor control or a heavy influx of shrimp, the application interval is more likely to be every three to four years (A. Schreiber, personal communication to J. Giddings, June 8, 2011).

Applications must be made between April 15 and December 15.

Oysters and clams may not be harvested within 30 days of application, and a 100 foot aerial application buffer or 25 foot ground application buffer must be maintained between treated areas and any adjacent untreated areas that may be harvested within 30 days.

The flowable product may be applied by air (helicopter only), backpack sprayer, or a ground based vehicle with boom. The granular product may be applied by air (helicopter only), handheld dispensers (“bellygrinders”), or a ground based vehicle with spinners or drop spreaders. The granular product may also be applied from a floating platform or boat. Aerial applications must be made to exposed beds at low tide. The labels include extensive spray drift management language governing droplet size, wind, temperature and humidity, and temperature inversions.

Material Safety Data Sheets for Mallet 2F and Mallet 0.5G, imidacloprid products identical to Protector 2F and Protector 0.5G, are attached in Appendices A and B.

3.3 Additional comments on efficacy and extent of use

Beyond the label requirements, there is a limited history of actual use experience for imidacloprid on shellfish beds. Various experimental methods were used in 2010 to apply imidacloprid at several rates to test efficacy and obtain various data on residues and non-target effects (Booth and Tufts 2010). For the flowable imidacloprid, these methods included ground applications by ATV and helicopter applications. Granular imidacloprid was applied with handheld granular dispensers (bellygrinders) or with a battery powered dry material, variable speed spreader mounted on an ATV or on a boat. Some applications were made to exposed beds. Other applications of granules from the boat or by handheld applicators were made when oyster beds were covered with 1-5 feet of water to enhance application to the substrate, rather than to prostrate eelgrass. Previous experimental work in 2008 (Booth et al. 2011a) indicated that flowable imidacloprid would be applied similarly to carbaryl (i.e., by helicopter or from a ground-based system that features a 27 ft. spray boom mounted on a semi-amphibious vehicle). In 2010, most applications were made in July and August, although two applications from a boat were made in October (Booth and Tufts 2010). However, application methods and equipment are under development to find more precise or effective means of control and may be employed within the conditions of the labels.

Previous use of carbaryl to control shrimp included applications in July and August at low tide to exposed beds, and by helicopter with boom sprayers (WDOE 2006). However, it is likely that imidacloprid applications will be spread out more within the labeled April 15-December 15 timeframe. It is also likely that granular imidacloprid may be applied when the eelgrass is covered with water and upright (Booth and Tufts 2010) because this appears to be most efficacious, thus allowing reduced total use throughout the treatment season.

The average acreage treated with carbaryl from 2003 through 2005 was 542 acres, less than is allowed under the carbaryl NPDES permit (WDOE 2006). In 2010, all told 489.1 acres were treated with carbaryl in Willapa Bay and Grays Harbor; except for one acre of experimental use, all applications were by helicopter in July (Booth and Tufts 2010). Over 3000 acres of privately owned oyster-growing tidelands have burrowing shrimp (WDOE 2006), and the Section 3 registration does not require a limit to the acreage that could be treated with imidacloprid.

4. Chemical Characteristics

The physical/chemical data in the following sections are those required by US EPA when a product is registered for use in the US as a pesticide. These characteristics assist in the basic understanding of the molecule and are later used in predicting environmental behavior or are considered when higher tiered studies are designed or requested. Pure active ingredient or technical grade active ingredient refers to the

active compound(s), which cause the desired biological effect when applied to a target system. The technical grade active ingredient is typically formulated into end-use products, also known as formulated products. The end-use products consist of a known percentage active ingredient plus a solvent or solid carrier and may include surface active components to aid in dissolution, emulsification, suspension, etc., of the active ingredient. Technical products such as imidacloprid are rarely the desired form in the end-use product. One method used to produce a useful end-use product is to combine the technical grade active ingredient with solvents or diluents and surface active ingredients to assist their distribution in the aquatic environment. These products are typically either aqueous solutions which easily disperse into water, or emulsifiable concentrates which use the surfactants to allow the active ingredient to mix easily with water and therefore disperse in the treated water body. Alternatively, the technical grade active ingredient may be manufactured into a solid granular form by impregnating clay granules or coating other types of carrier matrices, producing a formulation that is ready for application with no need for mixing or other preparation.

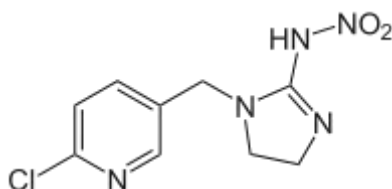
4.1 Composition of the imidacloprid end use products

The use of imidacloprid products Protector 2F (21.4% flowable) and Protector 0.5G (0.5% granular) is registered by the US EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The physical and chemical properties of these products are detailed alongside the active ingredient below. Several physical/chemical properties of Protector 2F and Protector 0.5G were obtained from the Material Safety Data Sheets (MSDSs) for Mallet (Appendices A and B), another imidacloprid end-use product. Protector and Mallet are chemically identical.

4.1.1 Active ingredients

Imidacloprid is a relatively complex molecule containing carbon, hydrogen, chlorine, nitrogen and oxygen. There exists a halide that could potentially contribute to persistent degradates/metabolites.

| | |
|--------------------|---|
| Common name: | Imidacloprid |
| CAS Registry No.: | 138261-41-3 |
| IUPAC name: | 1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine |
| Empirical formula: | C ₉ H ₁₀ ClN ₅ O ₂ |
| Molecular weight: | 255.7 g/mol |
| Structure: | |



4.1.2 Impurities

Studies on the identity of impurities, inerts, adjuvants, and manufacturing processes are considered proprietary and are not eligible for release under FOIA but are reviewed and considered by US EPA in the pesticide registration process.

There are no known impurities identified by the manufacturers or the US EPA which are known to be of toxicological or environmental concern. The US EPA has established guidelines that require that

impurities of concern, such as N-nitrosamines and chlorinated dioxins and furans must be disclosed. No such compounds are known to be present in the imidacloprid products.

All registered pesticidal end-use products (the products actually applied to the environment to control weeds or pests) must undergo a series of toxicological tests to establish their safety. Because these tests are performed on the actual end-use formulation, the effects of impurities are effectively tested simultaneously. This toxicological screen affords an additional opportunity to examine comparative data on the active ingredient versus the end-use product to determine if there is a need to test each of them in a complete testing battery.

4.1.3 Added inert ingredients

In the past, EPA assigned each inert ingredient to one of four lists representing different toxicity levels. While such inert ingredients are now regulated in a different manner, these lists are relevant to some imidacloprid data available in the public literature. They are as follows (US EPA 2004):

List 1: Inert ingredients of toxicological concern

List 2: Potentially toxic other ingredients/High priority for testing inerts

List 3: Inerts of unknown toxicity

List 4A: Minimal risk inert ingredients

List 4B: Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment

Since the nature of the inert components of imidacloprid is proprietary, there is little publicly available information (Anatra-Cordone and Durkin, 2005). The Protector 2F formulation contains propylene glycol (a List 4B inert) while Protector 0.5G contains N-methyl pyrrolidone (a List 3 inert). Neither formulation specifies the relative quantity of its identified inert compound.

A human case study in which a man attempted suicide by ingesting an imidacloprid-containing insecticide reported that the formulation contained 10% imidacloprid, less than 2% inerts, and 88% N-methyl-pyrrolidone solvent (Wu et al. 2001). Shiotsuka (1991) reported that chemically distinct forms of bentonite (a naturally occurring clay mineral, List 4A) are solid inerts in the 0.62 and 2.5% granular formulations.

The results of acute oral toxicity studies conducted on laboratory animals with imidacloprid and various imidacloprid formulations suggest that none of the inert components in the formulation are more toxic or potentiate greater toxicity than imidacloprid alone (i.e. the lowest LD₅₀ and NOAEL values were from studies conducted with technical grade imidacloprid), when exposure is short-term and oral. However, imidacloprid formulations produced mild to moderate eye and skin irritation according to human incident reports, while technical grade imidacloprid did not (Anatra-Cordone and Durkin, 2005).

4.1.4 Added synergists

There is no information or evidence that synergists are added to the imidacloprid formulation; known synergists are required to be indicated on pesticide labels.

4.1.5 Nature of formulation (e.g., powder, emulsifiable concentrate)

The Protector 2F formulation is a white liquid intended for dilution in water. The Protector 0.5G formulation consists of brown granules ready for application.

4.2 Color

Color is an endpoint observation of the product used to assist in identification.

Table 4.1. Color of imidacloprid and formulations

| Substance | Color | Citation |
|----------------|-----------|------------------|
| Imidacloprid | Off-white | EFSA 2011 |
| Protector 2F | White | Mallet 2F MSDS |
| Protector 0.5G | Brown | Mallet 0.5G MSDS |

4.3 Physical state

Physical state is an endpoint observation of the product, solid, liquid or gaseous used to assist in identification.

Table 4.2 Physical state of imidacloprid and formulations

| Substance | Physical State | Citation |
|----------------|----------------|------------------|
| Imidacloprid | Solid | FAO |
| Protector 2F | Liquid | Mallet 2F MSDS |
| Protector 0.5G | Granular solid | Mallet 0.5G MSDS |

4.4 Odor

Odor is an endpoint observation of the product used to assist in identification. Odor may also serve as a warning in cases where odorants are added as a safety factor.

Table 4.3 Odor of imidacloprid and formulations

| Substance | Odor | Citation |
|----------------|---------------------|------------------|
| Imidacloprid | Weak characteristic | Tomlin 2006 |
| Protector 2F | Sweet | Mallet 2F MSDS |
| Protector 0.5G | Weak characteristic | Mallet 0.5G MSDS |

4.5 Melting point

The melting point is a physical endpoint observation used for identification of pure compounds and may provide some indication of thermal stability. Melting point is not applicable to the 2F formulation because it is a liquid. Different values for the melting point of imidacloprid were found in literature review; the chosen value reflects the purest form of imidacloprid reported (99.9%).

Table 4.4 Melting point of imidacloprid and formulations

| Substance | Melting Point °C | Citation |
|----------------|------------------|------------------|
| Imidacloprid | 144 | EFSA 2006 |
| Protector 0.5G | N/A | Mallet 0.5G MSDS |

4.6 Boiling point

The boiling point is a physical endpoint observation for identification of pure compounds. The boiling point for pure imidacloprid is undefined because the chemical is a solid. The sublimation point for imidacloprid is also undefined, because the chemical is subject to decomposition prior to phase change. The decomposition temperature of 99.5% imidacloprid is > 200°C (EFSA 2006).

4.7 Density, bulk density or specific gravity

Density is a measure of the mass per unit volume of the product and is useful for physical identification or differentiation of two similar products. The value may also be needed to calculate application rates in some instances. Density is typically reported as grams per cubic centimeter at 25°C; however, values for the active ingredient were only found at 20°C and 23°C.

Table 4.5. Bulk density of imidacloprid and formulations

| Substance | Bulk Density in Water (g/cm ³) | Citation |
|----------------|--|----------------------------------|
| Imidacloprid | 1.54 (20°C, 23°C) | EXTOXNET 1995 and CEPA-DPR, 2006 |
| Protector 2F | 1.10 | Mallet 2F MSDS |
| Protector 0.5G | 0.74 | Mallet 0.5G MSDS |

4.8 Solubility

Solubility is a physical endpoint useful for understanding potential environmental impact. High water solubility is frequently associated with mobility and affects distribution in water and soil. This endpoint is determined for the active ingredient in a product and is reported as grams per 100 ml water at 20°C. The active ingredient is readily soluble in dichloromethane, acetone, acetonitrile, dimethylformamide and dimethylsulfoxide, but only slightly soluble in toluene and 2-propanol and almost insoluble in *n*-hexane. In demineralized water, imidacloprid is somewhat soluble with no dependence on the pH (EFSA, 2011).

Table 4.6. Solubility of imidacloprid and formulations

| Substance | Solubility in Water @ 20°C (g/100 ml) | Citation |
|----------------|---------------------------------------|------------------|
| Imidacloprid | 0.051 | EXTOXNET |
| Protector 2F | Dispersible | Mallet 2F MSDS |
| Protector 0.5G | Completely soluble | Mallet 0.5G MSDS |

4.9 Vapor pressure

Vapor pressure is a physical endpoint useful for understanding the distribution of the active ingredient between water/soil and air. High volatility is an indication of potential impact in the air compartment. This endpoint is determined for the active ingredient in a product and is typically reported as mm mercury (Hg) at a specified temperature. The value given by EXTOXNET is reported.

Table 4.7. Vapor pressure of imidacloprid

| Substance | Vapor Pressure @ 20°C (mm Hg) | Citation |
|--------------|-------------------------------|---------------|
| Imidacloprid | 1.5×10^{-9} | EXTOXNET 1995 |

4.10 Disassociation constant

Disassociation constant is a physical endpoint used to assess the distribution of the pure active ingredient in aqueous media. Imidacloprid shows very weak basic properties. Complete protonation only occurs in non-aqueous solutions of very strong acids. It is not possible to specify a pK value in pure aqueous systems (EFSA 2011).

4.11 Octanol/water partition coefficient

Octanol/water partition coefficient (K_{ow}) is a physical endpoint used to assess the potential of a compound to bioaccumulate in the environment. The value represents the ratio of concentration in octanol versus water at equilibrium at 21°C. Log K_{ow} values of less than 5 indicate low likelihood of bioaccumulation. An estimation of the K_{ow} by Tomlin (2006) determined $K_{ow} = 3.7$. The log $K_{ow} = 0.57$.

Table 4.8. Octanol-water partition coefficient of imidacloprid

| Substance | Octanol/Water Coefficient (K_{ow}) | Citation |
|--------------|--|-------------|
| Imidacloprid | 3.7 | Tomlin 2006 |

4.12 pH

pH is a physical endpoint used to identify the product and to assess its potential effects on the environment. It represents the concentration of hydrogen in a solution, hence can only be determined for liquid formulations.

Table 4.9. pH of imidacloprid and formulations

| Substance | pH | Citation |
|--------------|-----|----------------|
| Imidacloprid | - | |
| Protector 2F | 7-8 | Mallet 2F MSDS |

4.13 Stability

Stability is a chemical evaluation of the product to assess the potential effect of heat, light, metals and metal ions on the active ingredient. Imidacloprid is stable under normal handling and storage conditions for both formulations. It is advised to avoid storing formulations in excessive heat, as imidacloprid will undergo a strong exothermal reaction above 200°C (Mallet 2F MSDS). Under fire conditions, formulations may produce gases such as hydrogen chloride, hydrogen cyanide, and oxides of carbon and nitrogen.

4.14 Oxidizing or reducing action

Oxidizing or reducing action is an assessment of the potential for a compound to react with common oxidizers or reducers. The MSDS for Mallet 0.5G warns that strong oxidizing agents, bases, and acids are incompatible with the formulation. The MSDS for the 2F formulation states their incompatible materials as “not known.”

4.15 Flammability

Determination of flammability is a measurement of the temperature that will sustain a flame and is used to classify the product for hazard in storage and shipping. Determination of flammability is not required for technical grade products.

Table 4.10. Flash point of imidacloprid formulations

| Substance | Flash point °C | NFPA Rating | Citation |
|----------------|----------------|------------------------|------------------|
| Protector 2F | > 98.9 °C | 1 (slightly flammable) | Mallet 2F MSDS |
| Protector 0.5G | N/A | 1 | Mallet 0.5G MSDS |

4.16 Explodability

Determination of explodability is a measurement of the potential for a compound to explode when exposed to physical or thermal shock. Determination of explodability is not required for technical grade products. The imidacloprid molecule itself contains no explodable functional groups. The Protector 2F formulation contains a high weight percentage of the flammable solvent propylene glycol and would be expected to be explosive if the vapor concentration above the product were to reach appropriate concentrations. Care should be used when mixing and handling the product to avoid exposure to sparks or other ignition sources. There is no mention of explodability on either formulation's product label or MSDS.

4.17 Storage stability

Storage stability is the physical determination of the stability of the active ingredient when stored in its commercial packaging over extended time periods, usually one to two years or more. Imidacloprid products have been shown to be stable under normal storage conditions for periods of at least two years (EFSA 2011).

4.18 Viscosity

Viscosity is a physical endpoint measurement used to identify the product and to assess the ability of the product to be poured or pumped. The measurement is not required on technical grade products or on solid products. The viscosity is reported in centipoise (cP).

Table 4.11. Viscosity of imidacloprid and formulations

| Substance | Viscosity (cP @ 20°C) | Citation |
|--------------|--------------------------|----------------|
| Imidacloprid | - | |
| Protector 2F | 103.1 | Mallet 2F MSDS |

4.19 Miscibility

Miscibility is a physical assessment of the ability of a formulated product to mix with spray oils for use during application. Since the imidacloprid formulations are not labeled for application in oil, this data requirement is not applicable.

4.20 Corrosion characteristics

Corrosion characteristics require the physical observation/measurement of the effects of the product on the commercial packaging. For the imidacloprid formulations, no effect is anticipated on the containers for end use product packaging.

4.21 Dielectric breakdown voltage

Dielectric breakdown voltage is the physical measurement of the effect of an electric arc on the stability of the formulated product. This requirement applies only to formulations that are applied around electrical equipment or apparatus. As there is no likelihood of open electrical apparatus in the vicinity of treated shellfish beds, this test is not applicable.

5. Environmental Fate

5.1 Volatilization

The low vapor pressure of 1.5×10^{-9} mm Hg (EXTOXNET 1995) indicates that imidacloprid is nonvolatile. In addition, the low Henry's law constant of 6.5×10^{-11} atm m³/mole (Fossen, 2006) indicates that it has low volatility in water. Therefore, imidacloprid is unlikely to be dispersed in air over a large area from volatilization.

5.2 Hydrolysis

Hydrolysis refers to the chemical interaction of the pesticide with water as a mechanism of pesticide breakdown. While aqueous or aquatic persistence studies are sometimes conducted in natural water bodies, true hydrolysis studies are conducted in laboratories using sterile distilled or deionized water so that the chemical effects of an aqueous environment can be isolated from biological, sunlight, or sediment interactions.

Laboratory hydrolysis studies for EPA submission are typically performed with radiolabeled (¹⁴C) pure compound at three pH values (pH 5, pH 7, pH 9, corresponding to slightly acid, neutral, and mildly alkaline, respectively) in sterile water for a period of 30 days at 25°C. Sampling for breakdown products and the remaining concentration of parent material occurs at frequent intervals.

5.2.1 Half-life

The Environmental Fate and Effects Division (EFED) of US EPA's Office of Pesticide Programs considers imidacloprid to be stable to hydrolysis (US EPA 2008b). A GLP study of imidacloprid hydrolysis was conducted at 3 nominal pH values and 25°C (Yoshida 1989). Slow hydrolysis with a half-life of approximately 1 year occurred at pH 9 and the half-life was greater than 1 year at pH 5 and 7. There is some evidence that wettable powder formulations can persist slightly longer (3-6 days) than liquid formulations.

5.2.2 Degradation products

The two major degradates via hydrolysis are 1-[(6-chloro-3-pyridinyl)methyl]-4,5-dihydro-1H-imidazol-2-amine] (IMI-guanidine) and 6-chloro-3-pyridyl-methylethylendiamine (Mobay 1989 as cited in Bacey 2000). Zheng and Liu (1999) found the only main degrade was 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidone.

Information on the half-lives of degradates was not found. It is noted that all degradates are less toxic than the parent compound, with no indication that any degradates experience significantly longer residence times (Suchail et al. 2001).

5.3 Aqueous photolysis

As with hydrolysis, photolysis testing is carried out in a laboratory. Vessels containing solutions of the test substance in sterile distilled or deionized water are irradiated with either a mercury vapor lamp or with natural sunlight. Identical vessels are kept in the dark for the duration of the study and also sampled in order to compensate for the effects of any hydrolysis occurring. Testing is usually carried out at 25°C, at pH 5, 7 and 9, but this is not always the case, particularly with early studies. Other photolysis testing, such as photolysis of a pesticide on the surface of a soil, is also required by the EPA for products that might be incidentally applied to soil, as is the case for imidacloprid.

The purpose of photolysis experiments is to isolate the effect of sunlight, specifically the ultraviolet and near-ultraviolet part of the spectrum, on the degradation of a pesticide without biological or chemical interactions. Natural sunlight's visible spectrum covers wavelengths from about 800 nm (deep red) to about 300 nm (deep violet). Generally speaking, only light in the violet and ultraviolet end of the spectrum has enough energy to initiate or influence chemical reactions ("photochemical reactions"). Air and ozone strongly filter near-ultraviolet and ultraviolet radiation, and cut off nearly all radiation below 290 nm wavelength. Water is transparent to radiation down to approximately 180 nm (far ultraviolet), assuming that there are no suspended solids or dissolved colored material such as humic acids to impair passage of the light.

The photodegradation of [pyridinyl-¹⁴C-methyl]imidacloprid was studied in sterile water, under the conditions of maximum hydrolytic stability (pH 7 at 23°C, Anderson 1991). Imidacloprid (5.4 mg/l) was continuously irradiated with a sunlight-simulating xenon lamp. The half-life of the photodegradation was 57 min. Based on this half-life, the environmental half-life was estimated at about 4.2 hours. Similarly, imidacloprid was degraded quickly (~ 4h) under natural sunlight in the greenhouse. The major photodegradation products were IMI-desnitro (17.2%) and IMI-urea (10 % of the applied radioactivity).

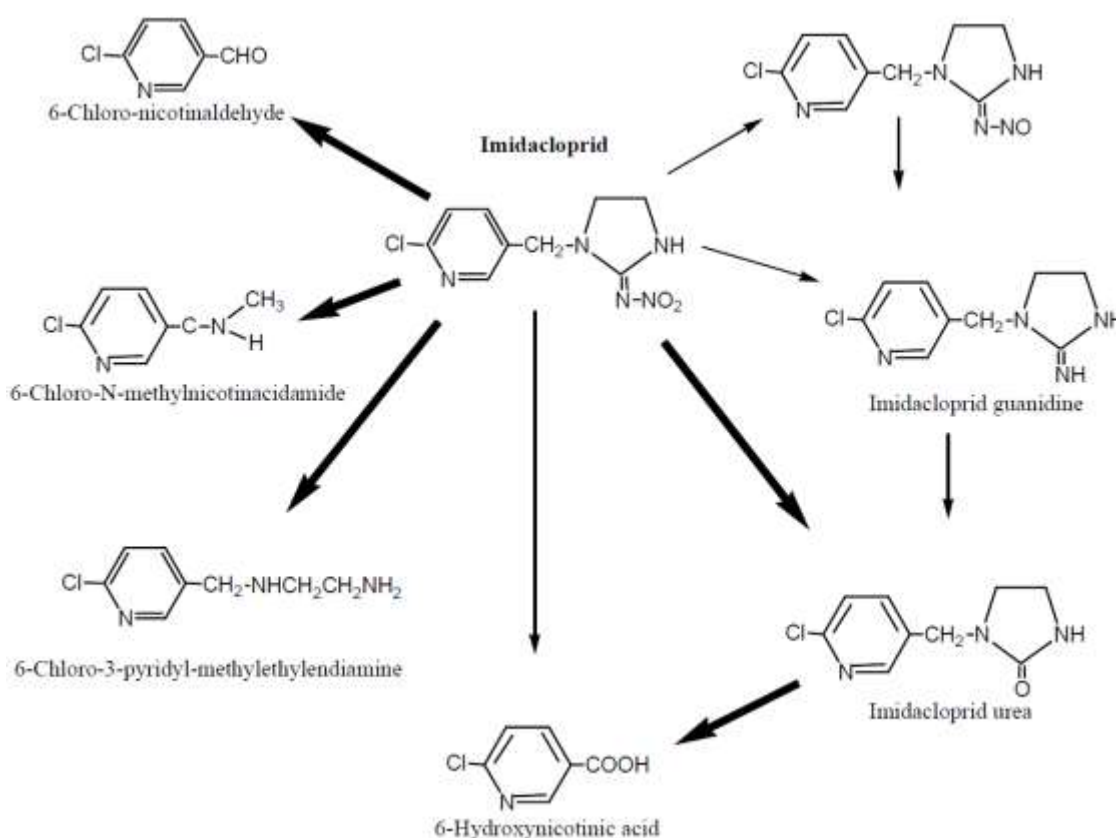


Figure 5.1. Imidacloprid photolysis products in water. Source: Bacey, 2001.

5.4 Soil photolysis

Soil photolysis is measured in the laboratory by exposing a thin layer of soil containing the radiolabeled active ingredient to either artificial or natural sunlight. The exposed soil is usually extracted to determine the amount of parent compound and any degradates that are extractable. Additional effort is typically

made to do an exhaustive extraction to remove as much of the residue as practicable, especially in the case of compounds such as imidacloprid which bind strongly to soil. The soil extracts are examined to determine qualitatively and quantitatively the nature and amount of remaining parent and degradates.

Photodegradation of [pyridinyl-¹⁴C] imidacloprid was investigated on sandy loam (Yoshida, 1990). The compound was applied at a concentration of 48.5 mg/kg onto the soil layer. It was then continuously irradiated with a sunlight-simulating xenon lamp for 15 days at 25°C. Imidacloprid degraded with a half-life of 38.9 days under the experimental conditions. The reported environmental half-life was 171 days, after adjusting for difference between lab irradiation and natural sunlight. The major photodegrade was 5-hydroxy imidacloprid.

5.5 Degradation and persistence – soil

To aid the understanding of the degradation of pesticidal products in the environment, studies of aerobic and anaerobic soil metabolism are normally required for each registered product. These studies are conducted in the laboratory using radiolabeled pure active ingredient. The half-life of the parent compound is monitored as well as the formation and decline of any metabolites/degradates.

The aerobic study is typically conducted on four soil types in an aerobic (oxygen rich) environment over a sufficient time period to allow the collection of sufficient data to measure the half-life and determine the metabolic fate of the compound. The anaerobic soil metabolism study is initiated in the same manner as the aerobic study, but is made anaerobic (oxygen-deficient) after 30 days either by flooding with water or by a continuous purge of nitrogen to exclude oxygen from the system. Half-life of the parent compound and its metabolic fate are determined as in the aerobic study.

5.5.1 Half-life

Registrant-sponsored studies in northern Europe found the mean dissipation time (DT₅₀) was 174 days in bare soil, while cropped conditions reduced it to 83 and 124 days (Krohn and Hellpointner 2002). It is likely that persistence in vegetated areas is decreased through plant (Rouchaud et al. 1994) and microbial (Capri et al. 2001; Krohn and Hellpointner 2002) uptake and metabolism.

The half-life of imidacloprid in soil tends to increase as soil pH increases (Sarkar et al. 2001) and as exposure to light decreases. In darkness, the longest half-life observed was 229 days in the field and 997 days in the laboratory. Its persistence in soils (due to shielding from light) makes imidacloprid suitable for seed treatment and incorporated soil application because it allows continual availability for uptake by roots (Mullins, 1993).

5.5.2 Degradation products

The primary imidacloprid breakdown products in soil are IMI-urea, 6-hydroxynicotinic acid, and 6-chloronicotinic acid (Rouchaud et al. 1992). CO₂ is then formed from 6-chloronicotinic acid (Scholz and Spiteller 1992). A proposed metabolic pathway for aerobic degradation of imidacloprid in soil is given below.

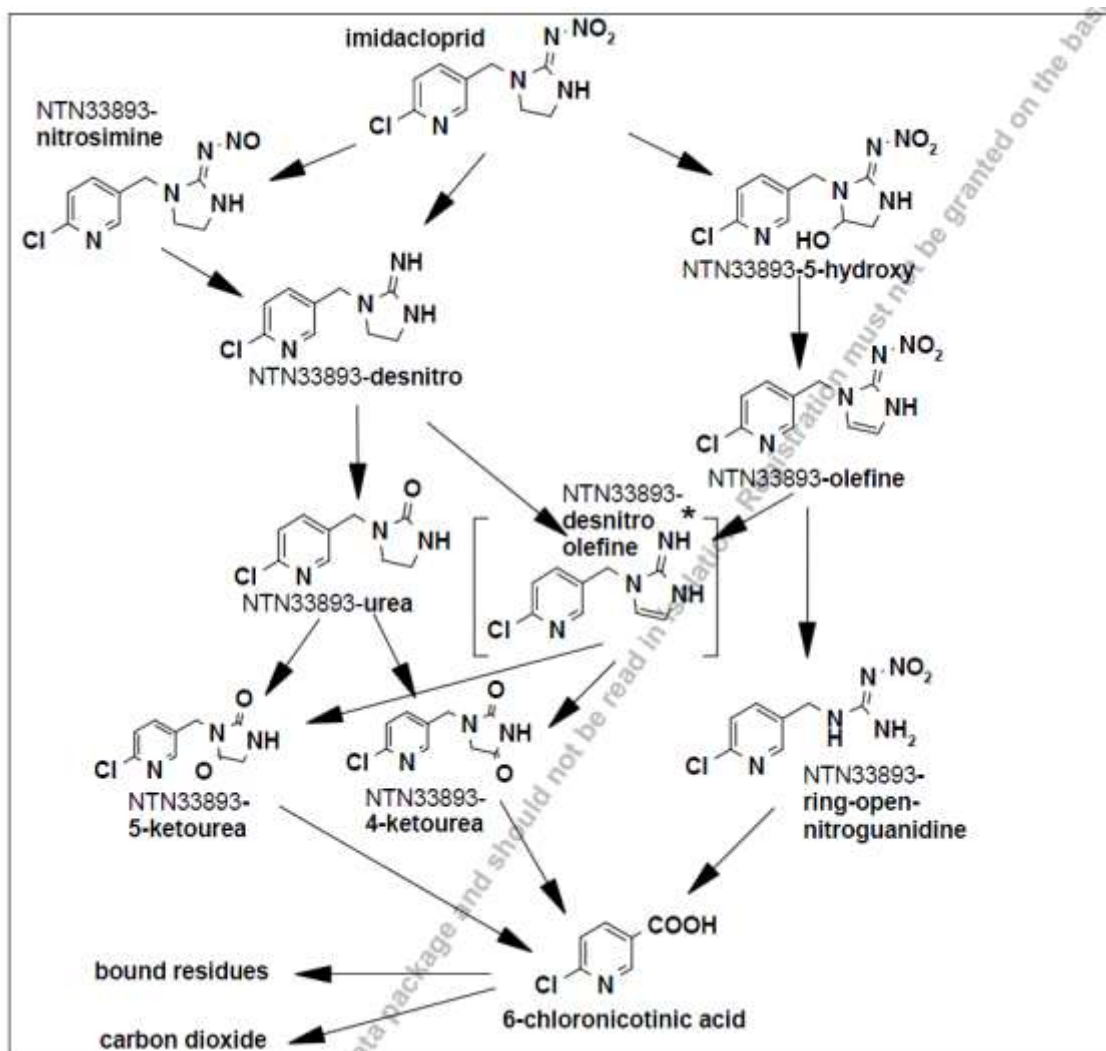


Figure 5.2. Proposed metabolic pathway for the aerobic degradation in soil of imidacloprid¹. Source: EFSA 2006.

5.6 Degradation and persistence - aquatic systems

The disappearance of imidacloprid from a lake or other natural water body is influenced by a number of factors. Water chemistry conditions, physical conditions such as temperature, adsorption to the sediment, water currents and dilution can all have pronounced effects on the persistence of imidacloprid.

5.6.1 Half-life and disappearance time

In the aqueous environment, imidacloprid is metabolized by microorganisms (CCME 2007). Disappearance half-time (DT_{50}) values of 30, 130 and 160 days have been calculated in the absence of light and with different sediments (Krohn and Hellpointer 2002). Combining metabolic and photolytic processes reduces the DT_{50} values to the range of days (Heimbach and Hendel 2001, cited in Krohn and Hellpointer 2002). Spiteller (1993) examined the degradation of imidacloprid in a 30-day laboratory study using water and sediment collected from a pond. Radiolabeled imidacloprid was applied to the water at an initial rate of 680 µg/L. By the end of the exposure, 67.6% of the radioactivity remained in the water column, with 64.0% as parent imidacloprid and 3.6% as degradates. In the sediment, 29.3% of the

¹ Watermark reads, "WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document."

radioactivity was detected, with 20.4% as extractable parent imidacloprid, 0.7% as extractable degradates, and 8.2% as bound residues. There was also 0.7% of the radioactivity detected as CO₂, and <0.1% as other volatile degradates. Therefore, after 30 days, little biodegradation had occurred, and a DT₅₀ for imidacloprid of 129 days was estimated (Spiteller 1993). A similar study with pond water and sediment was conducted by Henneböle (1998) to determine the influence of exposure to either artificial light (xenon lamp) or sunlight on degradation of imidacloprid. When applied to the water at an initial rate of 620 µg/L, the half-life of the radiolabeled imidacloprid was estimated at less than 14 days. After 21 days, 5.8% of the imidacloprid had been mineralized in the exposure to sunlight, and 9.8% had been mineralized in the exposure to xenon light. Residues bound to the sediment at 21 days accounted for 67.6% of the applied radioactivity in the sunlight exposure, and 47.7% in the xenon light exposure (Henneböle 1998). Anaerobic metabolism in the absence of light was measured at a DT₅₀ of 27 days (Krohn and Hellpointer 2002).

A limited number of measurements have been made on the persistence of imidacloprid under field conditions associated with the uses discussed in this current review. An integrated pest management program for burrowing shrimp that includes imidacloprid applications on commercial shellfish beds in Willapa Bay and Grays Harbor has been under experimental development since 2008 (Grue et al. 2011; Grue and Grassley 2013). This program has included monitoring of imidacloprid concentrations in the water column, sediments and in pore water. Although a standard half-life cannot be calculated from these data, they do provide additional information on the relative persistence of imidacloprid under actual use conditions. The presence of imidacloprid in the water column above treated beds is rapidly reduced through dilution and tidal flushing, with residues below detection limits within 72 hours. In the only trial providing adequate time intervals between samples, imidacloprid residues (mean values) in bed sediments were reduced from initial post-application values of 593 ppb to 6 ppb in 28 days. Sediment pore water concentrations declined from a post-application high of 188 ppb to 0.4 ppb by 28 days. These results suggest that in the estuarine environment, dissipation is relatively rapid in the water column, sediments and sediment pore water. This may be associated with a number of factors unique to this environment including constant water movement, rich microflora and burrowing actions of macroinvertebrates.

5.6.2 Degradation products

In general, degradation in aquatic systems will include elements of hydrolysis, photolysis, and soil and microbial degradation. Two studies incorporating these elements were submitted by EFSA and found a total of six degradates: IMI-5-hydroxy, IMI-nitrosimine, IMI-urea, 6-chloronicotinic acid, IMI-PEDA, and IMI-desnitro (Spiteller 1993; Wilmes 1990). The Wilmes study found an IMI-desnitro concentration of 12.3%, the only major degradate of either study. Tables 5.1 and 5.2 show more detailed results of these studies. Under dark, anaerobic conditions, IMI-desnitro is produced. IMI-desnitro is more persistent than its parent compound (Fritz and Hellpointer 1991) and is highly water soluble (180-230 g/L) (Krohn 1996).

Table 5.1. Pattern of metabolites in water samples as a function of time (determined by TLC, in % of the radioactivity initially applied)

| Incubation Period | Parent | IMI-5-hydroxy | 6-hydrox-nicotinic acid | IMI-nitrosimine | IMI-urea | Scattered Activity | Total |
|--------------------|--------|---------------|-------------------------|-----------------|----------|--------------------|-------|
| Water Phase | | | | | | | |
| Day 0 | 90.7 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 0.7 | 91.4 |
| Day 3 | 77.2 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 0.3 | 77.5 |
| Day 7 | 69.4 | 2.4 | < 0.1 | < 0.1 | < 0.1 | 0.2 | 71.9 |
| Day 14 | 67.8 | 0.9 | 0.5 | 0.7 | 0.4 | 0.2 | 70.6 |
| Day 21 | 66.0 | 1.4 | 0.7 | 0.9 | 0.7 | 0.5 | 70.1 |

| | | | | | | | |
|-----------------|------|-------|-------|-------|-------|-------|------|
| Day 30 | 64.0 | 1.4 | 0.9 | 0.6 | 0.9 | 0.3 | 67.6 |
| Sediment | | | | | | | |
| Day 0 | 7.6 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 7.6 |
| Day 3 | 19.3 | 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 | 19.5 |
| Day 7 | 23.5 | 0.4 | < 0.1 | < 0.1 | < 0.1 | 0.1 | 24.0 |
| Day 14 | 22.1 | 0.3 | < 0.1 | < 0.1 | 0.1 | 0.1 | 22.6 |
| Day 21 | 19.0 | 0.4 | < 0.1 | < 0.1 | 0.2 | < 0.1 | 19.6 |
| Day 30 | 20.4 | 0.4 | < 0.1 | < 0.1 | 0.2 | 0.1 | 21.1 |

Source: Spiteller (1993). From EFSA 2006 p. 700.

Table 5.2. Pattern of metabolites as a function of time (determined by TLC, in % of the radioactivity initially applied) for system IJzendoorn (mean from two incubation vessels)

| Incubation Period | Parent | IMI-desnitro | 6-chloro-nicotinic acid | IMI-PEDA | unidentified |
|--------------------|--------|--------------|-------------------------|----------|--------------|
| Water Phase | | | | | |
| Day 0 | 78.5 | n.d. | 0.7 | n.d. | 1.5 |
| Day 14 | 41.2 | 0.8 | 1.1 | 0.2 | 1.1 |
| Day 29 | 26.8 | 2.3 | 0.9 | 0.3 | 0.8 |
| Day 60 | 9.8 | 4.4 | 0.5 | 0.4 | 0.7 |
| Day 92 | 5.1 | 6.0 | 0.3 | 0.3 | 0.8 |
| Sediment | | | | | |
| Day 0 | 13.5 | n.d. | n.d. | n.d. | 0.3 |
| Day 14 | 31.9 | 1.1 | 0.1 | n.d. | 0.3 |
| Day 29 | 22.8 | 3.0 | 0.2 | n.d. | 0.4 |
| Day 60 | 13.6 | 5.6 | 0.4 | n.d. | 0.4 |
| Day 92 | 6.6 | 6.3 | 0.3 | n.d. | 0.4 |

Source: Wilmes (1990). From EFSA 2006 p. 704.

Six imidacloprid degradates have been identified as having significant potency to invertebrate or vertebrate organisms: IMI-olefin, 5-OH-IMI, IMI-nitrosimine, IMI-guanidine, IMI-guanidine-olefin, and acyclic derivative. These compounds maintain the nitroguanidine moiety of imidacloprid, hence may possess equivalent or greater binding affinity for invertebrate or vertebrate nAChRs compared with the parent compound (Kanne et al. 2005).

Degradates have not been identified at Willapa Bay and Grays Harbor. It is reasonable to assume a similar distribution to the Spiteller and Wilmes studies. Toxicity levels of all degradation products are significantly below the parent compound.

5.7 Microbial degradation

Microbial degradation of imidacloprid is discussed in Sections 5.5 and 5.6.

6. Environmental Effects

6.1 Objectives

The objective of this section is to present an overview of available ecological toxicity data on imidacloprid. Subject areas to be emphasized are those related to the proposed uses of imidacloprid on shellfish beds (i.e., effects on fish and other marine/estuarine species). Birds and mammals will also be

addressed. This section presents data from laboratory tests along with the limited amount of field data that is available and relevant to this assessment.

6.2 Mobility

When a chemical is applied to soil, a potential exists for the chemical to be carried down through the soil with water movement from rain and irrigation. Pesticides exhibit a wide range of leaching potential, from those that adsorb strongly to soil particles and are not released before they break down, to those that do not adsorb significantly (or adsorb, then desorb) and travel considerable distances down through the soil, sometimes as far as the ground water table. Different chemicals are affected in different ways by soil parameters such as organic matter, clay content and type, and pH.

6.2.1 Soil

Organic matter is the controlling sorptive medium for imidacloprid in soil (Liu et al. 2006). Based on its organic carbon-water partitioning (K_{OC}) values, imidacloprid would have medium mobility, with K_{OC} s ranging from 161 to 256 mL/g (US EPA 2008a).

6.2.2 Sediment

Sources used for this document did not report mobility of imidacloprid in sediment. The information presented for mobility in soil is applicable to sediment.

6.2.3 Groundwater

Two small scale prospective ground water monitoring studies in Michigan and California found that imidacloprid and some of its degradates leached through the soil during water infiltration periods. The California study reported control samples bearing imidacloprid concentrations of 0.05 and 0.10 µg/L in groundwater. The Michigan study found imidacloprid to be leaching at a variable rate and concentration. Detectable residues were found in most groundwater samples 319 days after treatment. The maximum parent concentration detected at any one site was 0.24 µg/L.

These concentrations are thousands of times below levels for which US EPA has expressed concern.

No groundwater leaching is anticipated in Willapa Bay and Grays Harbor, as imidacloprid on treated beds will quickly dissipate by water movement within the estuary.

6.3 Sources of information

A wide range of data sources provided information on the toxicity of imidacloprid to marine/estuarine species. One primary source of information was the US EPA, which has developed a number of documents related to the registration review of imidacloprid (e.g., EFED Problem Formulation for the Registration Review of Imidacloprid [US EPA 2008b]). Additional data were available in US EPA's ECOTOX database (<http://cfpub.epa.gov/ecotox/>). The following five online databases were also searched for data of interest: PubMed (<http://www.ncbi.nlm.nih.gov/pubmed/>), Google (<http://www.google.com>), Google Scholar (<http://scholar.google.com/>), Wiley Online Library (<http://onlinelibrary.wiley.com>), and the Society of Environmental Toxicology and Chemistry's journal database (<http://www.setac.org/>). Finally, available imidacloprid toxicity reviews (e.g., CCME [2007]) were retrieved and their data were compared to the data retrieved from the other data sources to ensure that all publically-available data were identified in this search.

Additional unpublished data were supplied by scientists from Washington State University, University of Washington and the Pacific Shellfish Institute. These data were only available in unpublished reports.

They include a number of laboratory and field studies that were conducted to evaluate the toxicity of imidacloprid to invertebrates and vertebrates living in estuarine and marine habitats. The experiments were done in support of various imidacloprid registration submissions, academic investigations and for local evaluations of compound effects associated with limited use permits. A number of species including fish, crustaceans, mollusks and polychaetes were used as test organisms. Some studies used standardized protocols employing accepted test species and Good Laboratory Practice (GLP) standards reporting requirements, while others were conducted under less rigorous guidelines.

6.4 Toxicity information

6.4.1 Microbes

There is no indication that imidacloprid is likely to cause adverse effects on estuarine/marine microorganisms since imidacloprid is metabolized by microorganisms in aqueous environments (CCME 2007). In a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant, a NOEC of 5,600 mg/L and an EC₅₀ > 10,000 mg/L were determined (EFSA 2011). Liu et al. (2001) reported that imidacloprid (up to 0.100 mg/L) and its degradates (up to 0.04 mg/L) had little effect on soil microorganisms.

6.4.2 Algae

No studies were available to assess the toxicity of imidacloprid to marine algae. However, freshwater data indicate that algae are at least three orders of magnitude less sensitive to imidacloprid than many insect and crustacean species (CCME 2007).

6.4.3 Aquatic macrophytes

As discussed in Sections 6.4.2, imidacloprid is an insecticide and has low toxicity to plants. In field trials, Patten et al. (2011b) reported that eelgrass became established quickly on bare plots treated with 0.4 and 0.5 lb a.i./acre, indicating that eelgrass is capable of rapid growth when burrowing shrimp are reduced. Although no other studies of imidacloprid toxicity to aquatic macrophytes were available, it can be concluded that imidacloprid use on shellfish beds will not have adverse effects on aquatic macrophytes.

6.4.4 Fish

Eight laboratory toxicity studies of technical grade and formulations of imidacloprid on five species of marine/estuarine fish were identified by the search strategy described previously (Table 6.1). The studies ranged in length from 96 hours to 32 days. Imidacloprid has low toxicity to fish regardless of test species or duration. Toxicity studies on species that are resident in Willapa Bay and Grays Harbor indicate relatively low sensitivity to this product and reflect the results found with surrogate test organisms.

Table 6.1. Laboratory toxicity studies detailing imidacloprid effects on estuarine/marine fish

| Species | Reference | Duration | Protocol Details | Endpoints |
|--|-------------|----------|--|---|
| Sheepshead Minnow (<i>Cyprinodon variegatus</i>) | Ward 1990a | 96 h | Standardized EPA protocol; technical a.i. | LC ₅₀ ^a = 161 mg/L NOEC ^b = 58.2 mg/L |
| Sheepshead Minnow (<i>Cyprinodon variegatus</i>) | Grue, 2010a | 96 h | General static renewal protocol; 2F formulated product | LC ₅₀ = 60.6 mg/L |

| Species | Reference | Duration | Protocol Details | Endpoints |
|---|---------------------|----------|--|--|
| Sheepshead Minnow (<i>Cyprinodon variegatus</i>) | Grue, 2010a | 32 d | EPA static-renewal protocol; 2F formulated product | Endpoints include hatching success, growth and survival. EC ₅₀ ^c > 10 mg/L NOEC = 10 mg/L LOEC ^d > 10 mg/L |
| Chinook Salmon (<i>Oncorhynchus tshawytscha</i>) | Grue, 2010b | 96 h | EPA static-renewal protocol; 2F formulated product | LC ₅₀ = 108 mg/L |
| White Sturgeon (<i>Acipenser transmontanus</i>) | Grue, 2010b | 96 h | EPA static-renewal protocol; 2F formulated product | LC ₅₀ = 124 mg/L |
| Inland Silversides (<i>Menidia beryllina</i>) | Env. Canada, 2005 | 7 d | Env. Canada protocol; Technical a.i. | EC ₅₀ = 77.5 mg/L |
| Chinook Salmon (<i>Oncorhynchus tshawytscha</i>) | Frew and Grue, 2011 | 96 h | Standardized EPA protocol; 2 F formulated product | Lethargy in some fish > 66 mg/L; partial mortality noted at > 115 mg/L |
| Saddleback Gunnel (<i>Pholis ornata</i>) | Patten, 2011d | 96 h | General static renewal protocol; 2F formulated product | LC ₅₀ > 100 mg/L |

^aLC₅₀ = median lethal concentration

^bNOEC = No Observed Effect Concentration

^cEC₅₀ = median effective concentration

^dLOEC = Lowest Observed Effect Concentration

6.4.5 Aquatic invertebrates

The details of 17 laboratory toxicity studies of both technical grade and formulations of imidacloprid on marine/estuarine crustaceans, polychaetes, and mollusks were identified by the search strategy are presented below (Table 6.2). Relatively low acute and chronic toxicity was observed for mollusk and polychaete species. Specific crustaceans (i.e., Mysid Shrimp) are very sensitive to imidacloprid for both acute and chronic endpoints, while others (Dungeness Crabs) exhibit temporary immobilization (tetany) and lower mortality.

Table 6.2. Laboratory toxicity studies on imidacloprid effects on estuarine/marine invertebrates

| Species | Reference | Duration | Protocol Details | Endpoints |
|---|---------------|----------|---|---|
| Crustaceans | | | | |
| Mysid Shrimp (<i>Americamysis bahia</i>) | Ward 1990b | 96 h | Standardized EPA protocol; technical a.i. | LC ₅₀ ^a = 38 µg/L |
| Mysid Shrimp (<i>Americamysis</i>) | Lintott, 1992 | 96 h | Standardized EPA protocol; technical | LC ₅₀ = 36 µg/L |

| | | | | |
|---|--------------------|---|---|--|
| <i>bahia</i>) | | | a.i. | |
| Mysid Shrimp (<i>Americamysis bahia</i>) | Ward, 1991 | 21 d | Standardized EPA protocol; technical a.i. | NOEC ^b = 0.6 µg/L |
| Grass Shrimp (<i>Palaemonetes pugio</i>) | Key et al, 2007 | 96 h | General static renewal protocol; Technical a.i | LC ₅₀ (larvae) = 309 µg/L LC ₅₀ (adults) = 564 µg/L |
| Hooded Shrimp (<i>Cumella vulgaris</i>) | Patten, 2011a | 1 h exposure followed by clean water | General static protocol; 1 and 2-hr exposures | Temporary immobilization at 800 µg/L (after 1 hr exposure); 400 µg/L (after 2 hrs exposure) |
| Blue Crab (<i>Callinectes sapidus</i>) | Osterberg, 2010 | 24 h | General static protocol; Technical a.i | LC ₅₀ (megalopae) = 10.04 µg/L LC ₅₀ (juveniles) = 1112 µg/L |
| Dungeness Crab (<i>Metacarcinus magister</i>) | Patten, 2011a | 4 h and 18 h exposures followed by clean water | Non-standard protocol; Megalopae; Technical a.i.; | 108 h LC ₅₀ (4-h exposure) = 6500 µg/L; Temp tetany at 500 µg/L 104-h LC ₅₀ (18-hr exposure) = 2400 µg/L; Temp tetany at 500 µg/L |
| Dungeness Crab (<i>Metacarcinus magister</i>) | Patten, 2011a | 4 h and 20 h exposures followed by clean water for 18 d | Non-standard protocol; One year old crabs; Technical a.i.; | 4 hr exposure gave temp tetany at > 5 mg/L 20-hr exposure gave temporary tetany at > 1000 µg/L |
| Dungeness Crab (<i>Metacarcinus magister</i>) | Patten, 2011a | 4 h exposure followed by clean water for 86 h | Non-standard protocol; Young of the year crabs; Technical a.i.; | EC ₅₀ (mobility) = 1700-3700 µg/L depending on hours after treatment; Temp tetany > 1500 µg/L |
| <u>Polychaetes</u> | | | | |
| Marine Polychaete (<i>Nereis brandti</i>) | Patten, 2011a | 96 h | General static renewal protocol; Technical a.i.: | No mortality at 100 mg/L |
| <u>Mollusks</u> | | | | |
| Eastern Oyster (<i>Crassostrea virginica</i>) | Wheat & Ward, 1991 | 96 h | General static protocol; technical a.i. | NOEC = 145 mg/L |
| Pacific Oyster (<i>Crassostrea gigas</i>): diploid & triploid forms | Patten, 2011d | 24 h | General static protocol: Technical and formulated | No effect on survival at 4 mg/L or less |

| | | | | |
|--|---------------|---|---|--|
| Pacific Oyster (<i>Crassostrea gigas</i>): diploid & triploid forms | Patten, 2011d | 96 h exposure followed by clean water for 172 d | General static protocol followed by field enclosures: Formulated | No effect on growth at 1,000 mg/L No effect on set at 1,000 mg/L (diploid) and 20 mg/L (triploid) |
| Kumamoto Oysters (<i>Crassostrea sikamea</i>) | Patten, 2011d | 96 h exposure followed by clean water for 92 d | General static protocol followed by field enclosures: Formulated | No effect on growth at 100 mg/L |
| Manila Clams (<i>Venerupis philippinarum</i>) | Patten, 2011c | 48 h | General static protocol: Technical and formulated; | No effects at 500 mg/L |
| Manila Clams (<i>Venerupis philippinarum</i>) | Patten, 2011c | 96 h exposure followed by clean water for 76 d | General static protocol followed by field enclosures | No mortality or effect on growth at 100 mg/L |
| Japanese Oyster Drill (<i>Ocenebrellus inornatus</i>) | Patten, 2011a | 96 h | General static protocol: Technical a.i. | No mortality at 100 mg/L |

^aLC50 = median lethal concentration

^bNOEC = No Observed Effect Concentration

^cEC50 = median effective concentration

6.4.6 Sediment organisms

Some of the invertebrates included in Table 6.2 are benthic organisms living in or on sediments, but they were tested in water-only systems. No laboratory studies were found on the toxicity of imidacloprid in sediment to marine organisms. In the absence of sediment toxicity data, the risk assessment is based on sediment pore water concentrations compared with water-only toxicity data.

6.4.7 Biological field studies

A number of studies (Table 6.3) have been conducted using field observations on native biota associated with commercial applications of imidacloprid (0.5 lb a.i./acre, flowable and granular formulations) to oyster beds in Willapa Bay and Grays Harbor. Studies in treated beds found no impact on fish, slight impact on macroinvertebrates (mainly polychaetes), and mortality or tetany of a small number of Dungeness Crabs. Field trials also used ecological indices (absolute abundance, richness and diversity) to study the potential impact of imidacloprid applications. Absolute abundance of macroinvertebrates was affected in one small plot trial, but all other comparisons under commercial-use conditions showed no significant impact of imidacloprid treatment. Changes were observed in some indices, but there was no significant negative ecological impact. These results indicated that the impacts were limited and that the rapid dissipation of imidacloprid through degradation and tidal flushing would quickly reduce further risk. In addition, the extensive tidal transport of juvenile invertebrates provides a rapid re-introduction of individuals.

Table 6.3. Biological observations made after imidacloprid treatments of oyster beds in Willapa Bay and Grays Harbor

| Reference | Species | Exposure | Sampling | Endpoint |
|--------------------------|---|---|---|--|
| Patten 2011b | Staghorn Sculpin & Threespike Stickleback | 0.5 lb a.i./acre flowable sprayed over tidal pool | Observations made at 48 h post-treatment | No mortality noted in either species |
| Booth et al. 2011a | Endemic macro-invertebrates on oyster beds | Commercial treatment of 0.5 lb a.i./acre flowable | Sampling conducted on-bed 24 h post-treatment | -No mortality in fish -Small number of dead Neriid polychaete worms -Small number of Hermit, Rock & Dungeness crabs exhibiting tetany |
| Booth et al. 2011b | Analysis of 63 macro-invertebrates that inhabit local oyster beds | Commercial treatment of 0.5 lb a.i./acre flowable; treatments made to oyster beds | Sampling conducted pre-treatment and 28 d post-treatment. | Imidacloprid treatment did not significantly decrease abundance, richness and diversity (Simpson & Shannon) before and after treatment (temporal controls). These results were found when all taxa were combined and when individual groups (mollusks, polychaetes and crustaceans) were analyzed. |
| Booth et al. 2011c | Analysis of 61 macro-invertebrates that inhabit local oyster beds | Applications of 0.4 or 0.5 lb a.i./acre flowable on different treatment plots | No pre-treatment sampling; post-treatment sampling conducted 2 or 3 weeks and 8 months later in 2006 and 4 weeks later in 2007. | Diversity and abundance of invertebrates, especially polychaetes, was often lower in treated plots. Mollusks and crustaceans were less affected; crustaceans were both more abundant and taxonomically rich in treated plots than in the control plots in the 8-month post-treatment samples. |
| Rasmussen and Booth 2011 | Analysis of 61 macro-invertebrates that inhabit local oyster beds | Applications of 0.5 lb a.i./acre granular and 2.0 lb a.i./acre flowable on different beds | Sampling conducted pre-treatment and 14 d and 28 d post-treatment. | Absolute abundance of combined and separated groups increased over sampling. Species diversity decreased at the first observation, but rose to greater than pre-treatment levels by the sampling at 28 days |
| Patten 2011b | Juvenile Dungeness Crabs | Applications of 0.5 lb a.i./acre flowable over field cages | Observations of mortality made at 14 d | No significant mortality (5%) observed compared to untreated controls |

| Reference | Species | Exposure | Sampling | Endpoint |
|---|--|--|--|---|
| Patten 2011b | Juvenile Dungeness Crabs | Applications of either 0.5 lb a.i./acre granular or 2.0 lb a.i./acre flowable over field cages | Observations made at 24 and 172 h post-treatment | No significant tetany or mortality compared to controls |
| Patten 2011b | Dungeness Crabs – 1 and 2 yr classes | Applications of either 0.5 lb a.i./acre granular or 2.0 lb a.i./acre. flowable over field cages on large plots | Observations made at 48 and 72 h post-treatment | Mortality for the 0.5 lb a.i./acre application at 6 – 12% |
| Patten 2011b | Dungeness Crabs – Free roaming on oyster beds | Applications of either 0.5 lb a.i./acre granular or 2.0 lb a.i./acre flowable over oyster beds | Observations made at 2 and 3 d post treatment at low tide | One dead crab noted per acre of treated beds for the 0.5 lb a.i./acre application |
| Booth et al. 2011a,b; Rassmussen and Booth 2011 | Burrowing Shrimp | Commercial treatment of 0.5 lb a.i./acre flowable and granules | Sampling conducted at several times post-treatment | Decrease in the density of burrows varied with trials |
| Patten 2011b | Native eelgrasses | Commercial treatment of 0.4 and 0.5 lb a.i./acre to bare plots | Sampling conducted after four months in one study and 12 months in another | Quick establishment of grasses on treated plots indicated that reduction in burrowing shrimp allowed rapid grass growth |
| Patten 2011e | Megafauna, with focus on Dungeness Crabs; eelgrass | Commercial treatment of 0.5 lb a.i./acre flowable and granules | Sampling conducted at several times post-treatment, up to 14 d | Fish were not affected; slight impact on Dungeness Crabs (0-19 per plot). Eelgrass residues were not detected except in one sample (24 µg/kg) |
| Patten 2012 | Megafauna, with focus on Dungeness Crabs and fish | Commercial treatment of 0.5 lb a.i./acre | Sampling conducted 24 h post-treatment | Fish were not affected; slight impact on Dungeness Crabs (varied from 0.2-3.4 affected crabs/acre). |
| Patten 2013 | Megafauna, with focus on Dungeness Crabs | Commercial treatment of 0.5 lb a.i./acre flowable and granules | Sampling conducted at several times post-treatment, up to 14 d | Fish and birds were not affected; slight impact on Dungeness Crabs (2 per acre), with mortality from predation associated with tetany. |

6.4.8 Amphibians

Amphibians do not occupy salt water or tidal flats. The available freshwater toxicity tests have shown that imidacloprid has low toxicity to amphibian species (CCME 2007).

6.4.9 Toxicity to birds

Avian toxicity data for imidacloprid are presented in Table 6.4. Imidacloprid is considered acutely toxic to birds (CCME 2007).

Table 6.4. Avian toxicity endpoints for imidacloprid

| Species | Endpoint | Value | Reference |
|------------------------|--------------------------------|----------------------------------|---------------|
| House Sparrow – 28 g | Acute Oral LD ₅₀ | 41.0 mg a.i./kg body weight (bw) | US EPA 2009 |
| Bobwhite Quail – 178 g | Acute Oral LD ₅₀ | 152.3 mg a.i./kg bw | US EPA 2009 |
| Bobwhite Quail – 178 g | Acute NOAEL | 25 mg a.i./kg bw | Toll 1990 |
| Bobwhite Quail – 178 g | Acute Dietary LC ₅₀ | 1536 mg a.i./kg food | US EPA 2009 |
| Bobwhite Quail – 178 g | Chronic NOEC | 36 mg a.i./kg food | US EPA 2009 |
| Canary – 15 g | Acute NOAEL | 10 mg a.i./kg bw | Grau 1994a |
| House Sparrow – 28 g | Acute NOAEL | 3 mg a.i./kg bw | Stafford 1991 |
| Japanese Quail – 120 g | Acute NOAEL | 3.1 mg a.i./kg bw | Grau 1988 |
| Mallard Duck – 1580 g | Acute Dietary LC ₅₀ | >4797 mg a.i./kg food | US EPA 2009 |
| Mallard Duck – 1580 g | Chronic NOEC | 47 mg a.i./kg food | US EPA 2009 |
| Pigeon – 280 g | Acute NOAEL | 12.5 mg a.i./kg bw | Grau 1994b |

6.4.10 Toxicity to mammals

Mammalian toxicity endpoints are shown in Table 6.5.

Table 6.5. Mammalian toxicity endpoints for imidacloprid

| Species | Endpoint | Value | Source |
|------------------------|-----------------------------|---------------------|-------------|
| Laboratory Rat – 350 g | Acute Oral LD ₅₀ | 424 mg a.i./kg bw | US EPA 2009 |
| Laboratory Rat – 350 g | Chronic NOEC | 250 mg a.i./kg food | US EPA 2009 |

6.4.11 Terrestrial plants

There are no phytotoxicity data for imidacloprid. The likelihood of exposure to terrestrial plants from application of imidacloprid to shellfish beds is minimal.

7. Ecological Exposure Assessment

7.1 Routes of exposure

The proposed imidacloprid applications may be made by helicopter, backpack sprayer, ground-based vehicle, or “belly grinder,” depending on which formulated product is used. The Protector 0.5G label informs applicators to avoid the use of spreaders that would concentrate the product into narrow bands.

Aquatic species within Willapa Bay and Grays Harbor will face some inherent acute exposure to imidacloprid for all application types, as tidal waters convectively disperse the compound. Additionally, some species may face exposure from ingesting exposed organisms. However, there is no reasonable concern for chronic exposure, as treatments are to be applied no more than once annually.

7.1.1 Aquatic plants and algae

Applications are made directly to water. Thus, the primary route of exposure for aquatic plants and algae would be through imidacloprid concentrations in the water. For applications made above the water, exposure to emergent plants could result from direct application. Based upon the octanol/water partition coefficient of imidacloprid, it would be expected that imidacloprid would not adsorb strongly to algae and

plants in the water. Therefore, the likelihood that imidacloprid would penetrate into plant cells and tissues is low.

7.1.2 Fish and other aquatic vertebrates; aquatic invertebrates

Applications are made directly to water. As with algae and aquatic plants, the primary route of exposure would be from imidacloprid in the water column. Fish and aquatic arthropods in the water column would take up imidacloprid through their gills; some dermal or oral uptake could also occur. Benthic organisms would be exposed through the sediment. Other vertebrates that may occur in or on the water would be exposed to imidacloprid either through dermal uptake or through ingestion of treated water or food items with imidacloprid residues.

7.1.3 Terrestrial Organisms

7.1.3.1 Amphibians

Significant exposure of terrestrial phase amphibians is not expected because amphibians do not inhabit salt water or tidal flats.

7.1.3.2 Birds

Birds could be exposed to imidacloprid by several routes:

1. Contact with imidacloprid residues in water, soil, and interstitial water in or adjacent to treated shellfish beds.
2. Direct ingestion of imidacloprid granules on treated shellfish beds.
3. Feeding on invertebrates, fish, and aquatic plants containing imidacloprid residues. For mobile dietary items, this exposure could occur at a distance from the treated shellfish beds.

It is assumed that ingestion of imidacloprid in dietary items is the main route of exposure for birds. Ingestion of salt water is not considered a significant route of exposure. Birds in contact with water or with the treated soil of the mudflat could acquire a dermal dose, but this route is probably insignificant because it would require the unlikely uptake through the feet or feathers.

The amount of exposure will vary depending on the location, habitat, and diet of particular bird species. This assessment will be based on focal species selected to represent species likely to be present in or around areas treated with imidacloprid.

Toxicity of imidacloprid to each focal species can be estimated based on standard toxicity test data for related surrogate species. Nearly all available toxicity data is for dietary exposure, which is considered the most important route of exposure for birds.

For a screening-level assessment, the risk of impact on each focal species can be characterized as the ratio of dietary exposure to toxicity (the Risk Quotient, RQ; US EPA 2004). RQs are compared with EPA's established Levels of Concern (LOCs), which are 0.2 for acute risk to non-endangered species, 0.1 for acute risk to endangered species, and 1 (based on chronic No Observed Adverse Effect Levels [NOAELs]) for chronic risk to non-endangered or endangered species. If the RQ for a focal species exceeds the corresponding LOC, there is an indication of a risk, but the inherent assumptions and conservatism of the assessment need to be evaluated before concluding that the risk is real.

As described above, imidacloprid will be applied in April through December, generally at low tide, at the rate of 0.5 lb a.i./acre to mudflats supporting shellfish beds. There will be only one application made per

year to each bed for a given crop of oysters, and usually the same area of the mudflat will only be treated every 3-4 years. Applications will be made with either a liquid or a granular formulation, by air or ground equipment. The spatial extent of aerial and ground applications will influence the potential for off-bed movement and exposure of birds to imidacloprid.

Imidacloprid applied to an exposed mudflat will reach the soil of the mudflat and any eelgrass that may be growing there. Shortly after application is completed, the incoming tide will inundate the mudflat soil. Residues of imidacloprid may occur in the water, on the mudflat soil, in interstitial water in the mudflat soil, in or on invertebrates that inhabit the mud, on eelgrass, and potentially in fish that swim over the treated bed as the tide rises.

The granular formulation may be applied to both exposed and inundated mudflats. When exposed mudflats are treated with the granular formulation, there will be a short period when birds could be exposed to the granules themselves. When inundated mudflats are treated, imidacloprid will be released from the granules in water or on the surface of the soil of the mudflat, and it is unlikely that birds will be exposed to the granules.

Imidacloprid will be applied to eelgrass in some shellfish beds, either when the eelgrass is submerged, or when it is recumbent when the tide is out. There are limited data on measured values for imidacloprid residues in eelgrass (See Table 8.7, section 8.1.1.3.2). As a worst case, it will be assumed that the Residue Unit Dose (RUD) for tall grass from Hoerger and Kenaga (1972) will apply. That RUD is 110 ppm per 1 lb a.i./acre, or 55 ppm for a 0.5 lb a.i./acre imidacloprid application. It seems likely that the residue on eelgrass should be considerably lower than the default value for tall grass. The eelgrass stems would be subjected to tidal flows daily and it is expected that imidacloprid would wash off the grass stems. Concentrations of imidacloprid would also be decreased due to growth dilution over the course of the season.

Focal Species

Avian focal species for the assessment were selected from those that have been observed to use the mudflats in Willapa Bay and Grays Harbor:

The Brant has been observed feeding on eelgrass on the tidal flats. It is intended to represent medium-sized waterfowl that work the tidal flats.

Seagulls (e.g., Heermann's gull) have been observed feeding on shrimp that have been "flushed" by carbaryl. Imidacloprid causes a tetanus-reaction, so shrimp may not be flushed from their burrows to the same degree as they would be by carbaryl. Crabs may also exhibit this tetanus reaction and become susceptible to predation by seagulls. Heerman's gull is intended to represent omnivores that work the tidal flats.

The listed Western snowy plover is known to inhabit Willapa Bay. It gets its food by probing soil or by picking invertebrates off the soil surface. Although this species normally forages along beaches, not on tidal flats, it is intended to represent small invertivores that work the tidal flats. A summary of the salient characteristics and endpoints used for the risk assessment follows in Table 7.1.

Table 7.1. Avian focal species selected

| Species | Family | Body Weight (g) | Toxicity Endpoints | Diet |
|----------------------|--------------|-----------------|--|----------------------------|
| Brant | Anatidae | 1370 | Mallard LC50 (converted to Median Lethal Dose [LD ₅₀]) Mallard NOEC | Eelgrass |
| Heermann's Gull | Laridae | 500 | House Sparrow LD ₅₀ Northern Bobwhite NOEC | Fish, crustaceans, mussels |
| Western Snowy Plover | Charadriidae | 41 | House Sparrow LD ₅₀ Northern Bobwhite NOEC | Aquatic Invertebrates |

7.1.3.3 Mammals

The assessment for mammals follows the assumptions made for birds quite closely. That is, dietary exposure is considered to be the most significant route, and exposure assessment is similar. The focal species selected is the raccoon, which has a diet of fish and aquatic invertebrates. The concentration of imidacloprid in these organisms is assumed to equal the maximum treated on-bed residue observed in water, 1.4 ppm (See Table 7.5, section 7.3.1).

Focal Species

Less is known about the mammals that may be foraging on the mudflats after application of imidacloprid than about the birds that forage there. The area of the tidal flat is exposed and offers animals little in the way of cover, so small mammals would be at risk of suffering predation by raptors; the small mammals would also have to be adapted to the saltwater environment. Considering the animals in the area and their likely feeding habits, it is believed that the raccoon would be a reasonable focal species. Key characteristics of this species are given in Table 7.2.

Table 7.2. Proposed focal species for assessing risk to mammals from applications of imidacloprid for control of burrowing shrimp in Grays Harbor and Willapa Bay, WA

| Species | Family | Body Weight (g) | Toxicity Endpoints | Diet |
|---------|-------------|---------------------------------|---|--------------------------------|
| Raccoon | Procyonidae | 3000 – 9000 (selecting 6000) | Acute Oral LD ₅₀ – Rat NOAEL -- Rat | Fish and aquatic Invertebrates |

7.2 Concentrations of imidacloprid

A number of field residue studies have been conducted on imidacloprid use in oyster beds located in the Willapa Bay and Grays Harbor waters of Washington State. Many of the studies were efficacy investigations associated with finding a replacement for carbaryl in control of burrowing shrimp species that reduce commercial production of oyster beds. Studies used a variety of protocols designed to answer information needs for local water permits, efficacy investigations and EUP applications. They were conducted over several years on different sites and employed various rates, formulations, application techniques and analytical measurements. While the heterogeneous nature of these studies makes it difficult to combine data, they provide residue concentration and dissipation trends that are very similar. They indicate a rapid decline in imidacloprid residues post-treatment in water, sediment and pore water. This is expected based on the known chemico-physical characteristics of imidacloprid, with high water solubility and rapid degradation in the marine environment. In addition, imidacloprid applications will be made to systems that are rich in microbial fauna, further enhancing metabolic degradation. Also, these aquatic systems receive a massive turnover of water daily associated with the tidal actions present. Major daily tidal fluctuations can range between six and ten feet.

7.2.1 Water column

In pre-2012 field trials, most peak measured imidacloprid concentrations in the water column over the treated area were 120 µg/L or less (Table 7.3). The highest imidacloprid concentration observed in these field trials was 1,400 µg/L, measured 2 hours after treatment with 0.5 lb a.i./acre flowable using a hand sprayer (Patten 2011e). The second highest concentration over a treated bed was 470 µg/L 1 hour after treatment with 0.5 lb a.i./acre granular (Booth et al. 2011b). In four other locations on the same bed, concentrations ranged from 0.08 to 27 µg/L, and the authors interpreted the single high value as an artifact of undissolved granular formulation. In the 2012 field studies (Grue and Grassley 2013; Hart Crowser 2013), concentrations at two sites over areas treated with the flowable formulation were 1,500 and 2,400 µg/L. Concentrations were lower, 73 and 490 µg/L, over the same areas treated with the granular formulation. The difference between results with the two formulations may be due in part to the fact that the granular formulation was applied while some water remained over the beds to reduce interception by eelgrass, resulting in greater dilution of imidacloprid. The value used in the risk assessment to characterize typical maximum on-bed imidacloprid concentrations in the water column was 2,400 µg/L.

Residues were also measured in waters adjacent to treated oyster beds. In some cases transects were designed to follow the direction of the incoming tide and in others samples were collected from adjacent channels. Most off-bed samples contained imidacloprid residues below 100 µg/L. In one trial with 0.5 lb a.i./acre flowable formulation applied by hand (Patten 2011e), a single off-bed sample contained 1,300 µg/L, while 7 other off-bed samples contained a maximum of 18 µg/L and 3 had no detectable imidacloprid at all. In another trial with 2.0 lb a.i./acre of flowable formulation, a maximum concentration of 700 µg/L was measured; adjusting this value to the proposed treatment rate of 0.5 lb a.i./acre results in an estimated peak of 175 µg/L. In the 2012 field studies (Grue and Grassley 2013; Hart Crowser 2013), water off beds treated with the flowable formulation contained from below the detection limit to 4,200 µg/L, with an average of 261 and 374 µg/L at two sites. Water off beds treated with the granular formulation contained much less imidacloprid, from below the detection limit to 130 µg/L, with an average of 2.4 and 17 µg/L at the two sites. The value used in the risk assessment to characterize typical maximum imidacloprid concentrations in the off-bed water column was 374 µg/L, the highest average for the two formulations and two sites.

Table 7.3. Imidacloprid residues in Willapa Bay and Grays Harbor water above treated oyster beds and in nearby water

| Reference | Rate & Formulation | Detection Limits (µg/L) | On-Bed Peak Water | On-Bed Dissipation | Off-Bed Peak Water | Off-Bed Dissipation |
|------------------------|------------------------------------|-------------------------|------------------------------|---|---------------------------|---------------------------------------|
| Felsot and Rupert 2002 | 1.0 lb a.i./acre; Technical | 0.5 | Not measured | Not measured | 17.7 µg/L | 0.6 µg/L by 24 h; non-detect by 28 d |
| Booth et al. 2011a | 0.5 lb a.i./acre; flowable | 0.02 | 120 µg/L | Non-detect by 24 h | 0.36 µg/L | Non-detect at next high tide |
| Booth et al. 2011b | 0.5 lb a.i./acre; granular | 0.02 | 0.08-470 µg/L (5 samples) | Non-detect to 0.06 µg/L (5 samples) by 30 h | 35 µg/L | Non-detect by 24 h |
| Booth and Tufts 2010 | 0.5 lb a.i./acre; granular | 0.02 | 120 µg/L | 0.52 µg/L by 30 h; non-detect by 78 h | 84 µg/L | 0.2 µg/L by 48 h; non-detect by 72 h |
| Booth and Tufts 2010 | 2.0 lb a.i./acre; flowable | 0.02 | 110 µg/L | 0.21 µg/L by 24 h; non-detect by 54 h | 700 µg/L | 0.38 µg/L by 48 h; non-detect by 72 h |
| Patten 2011e | 0.5 lb a.i./acre; granular; aerial | 0.02 | 27-82 µg/L (5 samples) | Non-detect by 6 h | 0-68 µg/L (4 samples) | No data |
| Patten 2011e | 0.5 lb a.i./acre; granular; boat | 0.02 | 16-31 µg/L (2 samples) | Non-detect by 54 h | 0-0.35 µg/L (5 samples) | No data |
| Patten 2011e | 0.5 lb a.i./acre; flowable; ATV | 0.02 | 4-19 µg/L (5 samples) | 0.15 µg/L by 6 h | 1.6-89 µg/L (8 samples) | No data |
| Patten 2011e | 0.5 lb a.i./acre; flowable; hand | 0.02 | 1,100-1,400 µg/L (2 samples) | Non-detect by 54 h | 0-1,300 µg/L (8 samples) | No data |
| Grue and Grassley 2013 | 0.5 lb a.i./acre; flowable | 0.04 | 1,500-2,400 µg/L (2 trials) | No data | 0-4,200 µg/L (36 samples) | No data |
| Grue and Grassley 2013 | 0.5 lb a.i./acre; granular | 0.04 | 73-490 µg/L (2 trials) | No data | 0-130 µg/L (19 samples) | No data |

7.2.2 Sediments

Grue et al. (2011) calculated that an application of 2.0 lb a.i./acre, dispersed through 10 cm of a hypothetical sediment with a specific gravity of 1.88 and 23.8% moisture, would result in 1,566 µg/kg dry sediment. This corresponds to 390 µg/kg for a 0.5 lb a.i./acre treatment. In two pre-2012 field trials with 0.5 lb a.i./acre applications (granular), measured concentrations of on-bed residues in the sediment were 0.13 µg/kg and 225 µg/kg, respectively (Table 7.4). A 1.0 lb a.i./acre trial resulted in on-bed sediment residues of 593 µg/kg, which would correspond to 296 µg/kg for a 0.5 lb a.i./acre treatment. In the 2012 field trials, imidacloprid concentrations in sediment in the treated area were lower, with the highest mean concentrations of 43 µg/kg for the flowable formulation and 30 µg/kg for the granular. A typical high-end value of 100 µg/kg was used to represent on-bed sediment concentrations in the risk assessment, based on

the weight of the evidence when considering all measured values. The only reported imidacloprid concentration in off-bed sediment was 0.003 µg/kg (Booth et al. 2011b).

Preliminary information on sediment pore water from the 2010 field trials (Table 7.4) indicated imidacloprid concentrations in on-bed pore water after 0.5 lb a.i./acre granular treatment were 100-200 µg/L (Grue et al. 2011). Correspondingly higher concentrations (300-1,200 µg/L) were measured after 2.0 lb a.i./acre flowable treatment. In both trials, off-bed pore water residues were considerably lower: 0.5-0.8 µg/L adjacent to the 0.5 lb a.i./acre granular treatment area and 0.8-4 µg/L adjacent to the 2.0 lb a.i./acre flowable treatment area (Grue et al. 2011). More complete results were obtained in the 2012 field trials (Grue and Grassley 2013; Hart Crowser 2013). On-bed pore water concentrations peaked at 2.1-118 µg/L for the flowable formulation and 14-65 µg/L for the granular formulation. A value of 100 µg/L was used to represent on-bed pore water concentrations in the risk assessment. Off-bed pore water concentrations 1 day after application of the flowable formulation averaged 3.0 and 5.6 µg/L at two study sites. Off-bed pore water concentrations were lower, 0.15 and 2.2 µg/L, after application of the granular formulation at the same sites. Off-bed pore water concentrations were represented as 5.6 µg/L in the risk characterization. This value was selected as the highest average concentration for the two formulations and two study sites in the 2012 field trials.

Table 7.4. Imidacloprid residues in Willapa Bay and Grays Harbor sediments and pore water in treated oyster beds and in nearby sites

| Reference | Rate & Formulation | Detection Limits (ppb) | On-Bed Peak Sediment | On-Bed Sediment Dissipation | On-Bed Peak Pore Water | On-Bed Pore Water Dissipation | Off-Bed Peak Sediment | Off-Bed Sediment Dissipation |
|------------------------|----------------------------|------------------------------------|---------------------------------------|--|------------------------------------|--------------------------------------|---|------------------------------|
| Felsot and Rupert 2002 | 1.0 lb a.i./acre; active | 2.5 | 593 µg/kg | 6.33 µg/kg by 28 d | Not measured | Not measured | Not measured | Not measured |
| Booth et al. 2011b | 0.5 lb a.i./acre; granular | 0.2 | 0.13 µg/kg | 0.01 µg/kg by 16 d | Not measured | Not measured | 0.003 µg/kg (bare mud), non-detect (eelgrass) | Non-detect by 16 d |
| Booth et al. 2010 | 0.5 lb a.i./acre granular | 0.2 ^a | 225 µg/kg (mean) ^b | 15 µg/kg by 24 h (mean) | ~100-200 µg/L ^b | 20 µg/L by 72 h and 0.4 µg/L at 28 d | Not measured | Not measured |
| Booth et al. 2010 | 2.0 lb a.i./acre flowable | 0.2 ^a | 80-370 µg/kg (2 samples) ^b | 14-15 µg/kg by 24 h; low levels remained at 28 d | 297-1,227 µg/L (2 sampling points) | 27-46 µg/L by 24 h | Not measured | Not measured |
| Grue and Grassley 2013 | 0.5 lb a.i./acre; flowable | 0.67 (sediment); 0.04 (pore water) | 8.1-43 µg/kg (3 trials) | 1.5-2.4 µg/kg at 28 d (3 trials) | 2.1-118 µg/L (3 trials) | 0.14-0.36 µg/L at 28 d (3 trials) | Not measured | Not measured |
| Grue and Grassley 2013 | 0.5 lb a.i./acre; granular | 0.67 (sediment); 0.04 (pore water) | 6.1-30 µg/kg (2 trials) | 0.30-0.54 µg/kg at 28 d (2 trials) | 14-65 µg/L (2 trials) | 0.10-0.18 µg/L at 28 d (2 trials) | Not measured | Not measured |

^a Value assumed from previous Booth et al. (2010) ELISA detection limit, not reported.

^b Values extrapolated from figures in Booth et al. (2010).

7.2.3 Adjacent terrestrial areas

Based upon the application methods, little or no exposure of adjacent terrestrial areas is expected.

7.3 Persistence and duration of residues

7.3.1 Water column

As observed in water residue samples, imidacloprid quickly dissipates after application through breakdown, dilution and tidal flushing (Table 7.3). On-bed and off-bed residues were below detection limits by 24–78 h.

7.3.2 Sediment and pore water

In field trials with the 0.5 lb a.i./acre application (granular), significant dissipation of sediment concentrations was observed by 24 h post-treatment (Table 7.4). All field studies of imidacloprid sediment residues showed significant dissipation, although terminal samples did not always drop to below detection limits. Pore water residues also declined rapidly.

7.3.3 Peak residues selected for risk assessment

Based on the relative consistency noted in these studies, a lower-tier risk assessment can be conducted using the worst-case residues for the 0.5 lb a.i./acre treatment as shown in Table 7.5.

Table 7.5. Typical maximum imidacloprid residues in field studies in Willapa Bay and Grays Harbor (0.5 lb a.i./acre treatment)

| Location | On Treated Oyster Bed | Adjacent Channels |
|----------------------|---|---|
| Acute Water Column | 2,400 µg/L | 374 µg/L |
| Acute Sediment | 100 µg/kg | 0.003 µg/kg |
| Acute Pore Water | 100 µg/L | 5.6 µg/L |
| Chronic Water Column | Chronic exposure not indicated; rapid dissipation | Chronic exposure not indicated; rapid dissipation |
| Chronic Sediment | 3.16 µg/kg at 28 d | Not measured |
| Chronic Pore Water | 0.4 µg/L at 28 d | Not measured |

7.4 Bioconcentration and bioaccumulation

Concentrations of imidacloprid in aquatic invertebrates and fish can be estimated assuming that tissue concentrations are in equilibrium with water concentrations. Imidacloprid has a low octanol-water partition coefficient ($\log K_{ow} = 0.57$), indicating a low potential for bioaccumulation. Indeed, because of the low $\log K_{ow}$, EPA has not required a bioconcentration study for imidacloprid. The $\log K_{ow}$ is below the minimum value required for EPA's Kabam bioaccumulation model. Assuming that imidacloprid is taken up from the water column or interstitial water rapidly, an estimate of residue concentrations in fish and invertebrate tissues would be the same as the maximum concentration in the on-bed treated water, 470 µg/L (Table 7.5).

Imidacloprid will be applied to eelgrass in some shellfish beds, either when the eelgrass is submerged, or when it is recumbent when the tide is out. There are limited data on measured values for imidacloprid residues in eelgrass (see Table 8.7, section 8.1.1.3.2). As a worst case, it will be assumed that the Residue Unit Dose (RUD) for tall grass from Hoerger and Kenaga (1972) will apply. That RUD is 110 ppm per 1 lb a.i./acre, or 55 ppm for a 0.5 lb a.i./acre imidacloprid application. It seems likely that the residue on eelgrass should be considerably lower than the default value for tall grass. The eelgrass stems would be subjected to tidal flows daily and it is expected that imidacloprid would wash off the grass stems.

Concentrations of imidacloprid would also be decreased due to growth dilution over the course of the season.

7.5 Ground and well water considerations

7.5.1 General aspects of groundwater and wells

There is no information on imidacloprid in groundwater and wells in treated areas or adjacent areas in Willapa Bay and Grays Harbor.

7.5.2 Mobility of imidacloprid and considerations for use in fractured basaltic areas

The potential movement of chemicals through fractured basaltic rocks and associated soils has become an issue in Washington as a result of studies at the Hanford site near Yakima, where contaminated plumes are approaching the Columbia River (Williams, et al, 2000). Movement of chemicals through fractured basaltic rocks is not a concern in coastal estuaries in western Washington.

8. Risk Assessment and Characterization for Ecological Effects

Risk characterization integrates exposure and effects data into an estimate of risk. In a lower-tier assessment, a risk quotient (RQ) is derived by dividing the environmental concentration, usually the estimated environmental concentration (EEC), of a chemical by the toxicity value, such as the LC₅₀ or No Observed Effect Concentration (NOEC) for a sensitive test species (US EPA 2004). US EPA has established Levels of Concern (LOCs) for comparison with the RQ. LOCs are set by policy to achieve certain results, such as protection of populations or protection of individuals (Table 8.1).

Table 8.1. Levels of Concern for pesticide risk (US EPA 2004)

| Risk presumption ¹ | RQ ² | LOC ³ |
|---|---|------------------|
| Acute risk - aquatic & terrestrial | EEC/LC ₅₀ or LD ₅₀ /ft ² | 0.5 |
| Acute restricted use – aquatic | EEC/LC ₅₀ or LD ₅₀ /ft ² | 0.1 |
| Acute restricted use – terrestrial | EEC/LC ₅₀ or LD ₅₀ /ft ² | 0.2 |
| Acute endangered species risk – aquatic | EEC/LC ₅₀ or LD ₅₀ /ft ² | 0.05 |
| Acute endangered species risk - terrestrial | EEC/LC ₅₀ or LD ₅₀ /ft ² | 0.1 |
| Chronic risk - aquatic & terrestrial | EEC/NOEC | 1 |

¹Acute risk at this level relates to effects on populations of non-target organisms.

Acute restricted use relates to classification of a pesticide to be used only by certified applicators.

Acute endangered species relates to effects on individuals of a T&E species.

²RQ = risk quotient; EEC= estimated environmental concentration; NOEC= no observed effect concentration.

The EC₅₀ may substitute for the LC₅₀ for aquatic invertebrates.

³LOC = Level of Concern established by US EPA for lower-tier risk assessment.

8.1 Effects

8.1.1 Aquatic organisms

Using typical maximum residue concentrations from imidacloprid field studies (Table 7.5), RQs can be calculated for marine and estuarine species in Willapa Bay and Grays Harbor (US EPA 2004). Acute and chronic toxicity values are available for a number of surrogate species of mollusks, crustaceans and fish representative of important species in Willapa Bay and Grays Harbor (Table 6.1 and Table 6.2).

8.1.1.1 Acute risk

Acute risk was estimated using comparisons between initial (peak) residues observed soon after application and the results of acute (e.g., LC50) toxicity results conducted under GLP or near-GLP conditions (Table 8.2 and Table 8.3). The analysis indicates that the proposed imidacloprid use is not expected to result in direct toxic effects to fish or mollusks living on treated beds and nearby channels in this area. Acute RQs for crustaceans exceed the Level of Concern (LOC = 0.1 for non-endangered species and 0.05 for endangered species, US EPA 2004), especially on the treated beds. Acute RQs for crustaceans are much lower off-bed in areas immediately adjacent to the treated areas. Acute RQs for all taxa are much lower in sediment pore water than in the open water, due to partitioning of imidacloprid to sediment particles (Grue and Grassley 2013; Hart Crowser 2013). Ecologically significant impact to crustaceans outside the treated area is unlikely due to the limited extent (spatially and temporally) of application to the bays and the rapid turnover of water and organisms associated with tidal flushing. It is worth noting that the surrogate species that exceed the LOC are related to the target species (burrowing shrimp). Impacts would be localized and transient, with rapid individual and species replacement.

Table 8.2. Acute Risk Quotients (RQs) for imidacloprid using residues from treated oyster beds (on-bed) and surrogate species for Willapa Bay and Grays Harbor. RQs in bold exceed the Level of Concern.

| Species | LC50 or EC50 (µg/L) | On-Bed Peak Water Residue (µg/L) | On-Bed Peak Pore Water Residue (µg/L) | On-bed Acute RQ Water | On-bed Acute RQ Pore Water |
|-------------------|-----------------------|----------------------------------|---------------------------------------|-----------------------|----------------------------|
| Eastern Oyster | >145,000 | 2,400 | 100 | <0.016 | <0.001 |
| Grass Shrimp | 309 | 2,400 | 100 | 7.8 | 0.32 |
| Mysid Shrimp | 36 | 2,400 | 100 | 66 | 2.8 |
| Blue Crab | 10 µg/L (megalopae) | 2,400 | 100 | 240 | 10 |
| | 1,112 µg/L (juvenile) | | | 2.2 | 0.09 |
| Sheepshead Minnow | 161,000 | 2,400 | 100 | 0.02 | 0.001 |
| Inland Silverside | 77,500 | 2,400 | 100 | 0.04 | 0.001 |

Table 8.3. Acute Risk Quotients (RQs) for imidacloprid using residues from channels adjacent to treated oyster beds (off-bed) and surrogate species for Willapa Bay and Grays Harbor. RQs in bold exceed the Level of Concern.

| Species | LC50 or EC50 (µg/L) | Off-bed Peak Water Residues (µg/L) | Off-Bed Peak Pore Water Residue (µg/L) | Off-bed Acute RQ Water | Off-bed Acute RQ Pore Water |
|-------------------|-----------------------|------------------------------------|--|------------------------|-----------------------------|
| Eastern Oyster | >145,000 | 374 | 5.6 | <0.003 | <0.001 |
| Grass Shrimp | 309 | 374 | 5.6 | 1.2 | 0.018 |
| Mysid Shrimp | 36 | 374 | 5.6 | 10.4 | 0.16 |
| Blue Crab | 10 µg/L (megalopae) | 374 | 5.6 | 37.4 | 0.56 |
| | 1,112 µg/L (juvenile) | | | 0.34 | 0.005 |
| Sheepshead Minnow | 163,000 | 374 | 5.6 | 0.002 | <0.001 |
| Inland Silverside | 77,500 | 374 | 5.6 | 0.005 | <0.001 |

8.1.1.2 Chronic risk

Less information is available for chronic risk analysis, with fewer toxicity endpoints (crustaceans and fish) for comparison to residue samples. The only chronic exposure is expected to be in on-bed sediment and pore water. There are no toxicity data for imidacloprid in sediments, so the chronic risk assessment is based on sediment pore water concentrations 28 days after application and chronic toxicity data for water-only exposures. Imidacloprid in on-bed pore water does not exceed the chronic LOC (1.0) for fish or for invertebrates (Table 8.4).

Table 8.4. Chronic risk quotients (RQs) for imidacloprid using residues from treated oyster beds (on-bed) and available surrogate species data for Willapa Bay and Grays Harbor.

| Species | NOEC (µg/L) | Chronic residues for pore water (µg/L) at 28 days – Highest value | Chronic RQ for pore water |
|-------------------|-------------|---|---------------------------|
| Grass Shrimp | 100 | 0.4 | 0.004 |
| Mysid Shrimp | 0.6 | 0.4 | 0.67 |
| Sheepshead Minnow | 2,300 | 0.4 | 0.0002 |

8.1.1.3 Risk to endemic species of Willapa Bay and Grays Harbor

Using a RQ analyses and residue concentrations associated with commercial use, imidacloprid does not show measureable risk to a variety of local species (Table 8.5 and Table 8.6). The acute RQ slightly exceeded the LOC for Pacific Oyster and Dungeness Crab on the treated bed and adjacent area. No other on-bed or off-bed water residue concentrations exceeded LOCs for endemic species of Willapa Bay and Grays Harbor. These findings are consistent with observations on fish and invertebrates during field trials with imidacloprid (Section 6.4.7; Table 6.3). In the field studies, fish and most macroinvertebrates were unaffected; polychaetes were reduced in treated areas; and a low level of mortality occurred in Dungeness Crab.

Table 8.5. Acute risk quotients (RQs) for imidacloprid using residues from treated oyster beds (on-bed) and species located in Willapa Bay and Grays Harbor. RQs in bold exceed the level of concern.

| Taxa | Species | LC50 or EC50 (µg/L) | On-bed Peak Water Residues (µg/L) | Acute RQ Water |
|-------------|-----------------------|---------------------|-----------------------------------|----------------|
| Mollusks | Pacific Oyster | 4,000 | 2,400 | 0.60 |
| | Kumomoto Oyster | 100,000 | 2,400 | 0.024 |
| | Manila Clam | 100,000 | 2,400 | 0.024 |
| | Japanese Oyster Drill | 100,000 | 2,400 | 0.024 |
| Crustaceans | Dungeness Crab | 1,700 | 2,400 | 1.4 |
| Polychaetes | Marine Polychaete | 100,000 | 2,400 | 0.024 |
| Fish | Saddleback Gunnel | 100,000 | 2,400 | 0.024 |
| | White Sturgeon | 77,500 | 2,400 | 0.031 |
| | Chinook Salmon | 108,000 | 2,400 | 0.022 |

Table 8.6. Acute risk quotients (RQs) for imidacloprid using residues from channels adjacent to treated oyster beds (off-bed) and species located in Willapa Bay and Grays Harbor.

| Taxa | Species | EC50 (µg/L) | Off-bed Peak Water Residues (µg/L) | Acute RQ Water |
|-------------|-----------------------|-------------|------------------------------------|----------------|
| Mollusks | Pacific Oyster | 4,000 | 100 | 0.025 |
| | Kumomoto Oyster | 100,000 | 100 | 0.001 |
| | Manila Clam | 100,000 | 100 | 0.001 |
| | Japanese Oyster Drill | 100,000 | 100 | 0.001 |
| Crustaceans | Dungeness Crab | 1,700 | 100 | 0.059 |
| Polychaetes | Marine Polychaete | 100,000 | 100 | 0.001 |
| Fish | Saddleback Gunnel | 100,000 | 100 | 0.001 |
| | White Sturgeon | 77,500 | 100 | 0.001 |
| | Chinook Salmon | 108,000 | 100 | 0.001 |

8.1.2 Terrestrial biota

In its review of the imidacloprid EUP for burrowing shrimp control, EPA (US EPA 2009) wrote: *No risks to terrestrial organisms are expected because the proposed uses are all in aquatic areas. No exposure should occur under the subsurface application method. Aerial application is made to exposed beds at low tide. These areas will be submerged later in the day at high tide. Any effects, if they occur at all, will likely be very much localized due to the small acreages under the current EUP and that the area will be submerged soon after application.*

Because the areal extent of imidacloprid use under the full EPA registration may increase compared to the approved use under the EUP, the risks to terrestrial animals and plants are reassessed below.

8.1.2.1 Birds

Food consumption as a function of body weight is estimated using allometric equations from the US EPA Wildlife Exposure Factors Handbook (US EPA 1993).

$$\text{For birds: } F = (0.648 \cdot BW^{0.651}) / (1 - W)$$

Where:

F = food consumption (g wet weight/d),
 BW = body weight (g), and
 W = water content of food item (default values are 0.80 for most food items and 0.20 for seeds).

Susceptibility as a function of body weight is estimated using the following equations (US EPA 1993):

For birds: Adjusted LD₅₀ = LD₅₀ * (AW/TW)^(x-1)

Where:

Adjusted LD₅₀ = size-adjusted toxicity endpoint of the focal species (mg a.i./kg bw)
 LD₅₀ = measured toxicity endpoint of a tested species (mg a.i./kg bw)
 Adjusted NOAEL = size-adjusted toxicity endpoint of the focal species (mg a.i./kg/d)
 NOAEL = measured toxicity endpoint of the tested species (mg a.i./kg/d)
 AW = weight of the focal species (g)
 TW = weight of the tested species (g)
 x = susceptibility factor (the default value is 1.15, Mineau et al. [1996])

To perform the acute assessment for the Brant, the LC₅₀ value for the mallard (>4794 mg a.i./kg food) was converted to an LD₅₀ based on the estimated food consumption rate of the mallard (0.3916 kg fresh weight/d). The resulting LD₅₀ for the mallard was >1082.9 mg a.i./kg. This conversion is conservative because it only accounts for consumption on 1 day of the 5-day LC₅₀ study. Because it could be argued that the mallards ate for 5 days, the actual exposure would have been 5X the 1-day value. Applying the adjustment for body weight, the estimated LD₅₀ for the Brant is >1059.9 mg/kg bw.

The resulting risk estimates for birds are shown in Table 8.7. All acute RQs are well below the listed species LOC of 0.1. Similarly, the chronic RQs for the Heermann's gull and Western snowy plover are below the listed species LOC of 1.0. The chronic RQ for the Brant is slightly above the listed species LOC. It is believed that this exceedance does not indicate a significant risk for 3 reasons. First, the estimate of imidacloprid residues on eelgrass is extremely conservative; the maximum residue observed in eelgrass during field trials was 24 µg/kg (Patten 2011e). Second, it is not likely that waterfowl would feed solely and exclusively on eelgrass on a treated shellfish bed, given that the beds are subject to tidal changes – flooding and subsidence—on a daily basis. Third, considering the Brant itself, it is common or abundant in the spring, but only occasionally or rarely occurs in Grays Harbor or Willapa Bay during the summer, when most applications of imidacloprid would likely be made (USGS 2011a, 2011b).

Table 8.7. Imidacloprid risk estimation for birds. RQ in bold exceeds the level of concern.

| Species | Bodyweight (g) | Food Consumption | Toxicity | Adjusted Toxicity | Estimated Exposure | RQ |
|--------------------------------|----------------|------------------|---------------|-------------------|--------------------|-------------|
| Brant – acute | 1370 | 356.9 g/day | >1089.9 mg/kg | >1059.9 mg/kg | 14.32 mg/kg/day | <0.01 |
| Brant – chronic | 1370 | -- | 47 mg/kg diet | 47 mg/kg diet | 55 mg/kg diet | 1.17 |
| Heermann's Gull – acute | 500 | 185.2 g/day | 41 mg/kg | 59.7 mg/kg | 0.52 mg/kg/day | 0.009 |
| Heermann's Gull – chronic | 500 | -- | 36 mg/kg diet | 36 mg/kg diet | 1.4 mg/kg diet | 0.039 |
| Western Snowy Plover – acute | 41 | 36.35 g/day | 41 mg/kg | 43.41 mg/kg | 1.24 mg/kg/day | 0.003 |
| Western Snowy Plover – chronic | 41 | -- | 36 mg/kg diet | 36 mg/kg diet | 1.4 mg/kg diet | 0.039 |

EPA has noted that some compounds can cause effects on avian reproduction (*via* altered behavior) after only a brief exposure. This phenomenon has been observed for organophosphates, but imidacloprid is not an organophosphate and does not inhibit acetylcholinesterase. The estimated acute imidacloprid exposure for the Brant is 100-fold lower than the LD₅₀, so short-term behavioral effects, if any, are likely to be negligible.

8.1.2.2 Mammals

Food consumption as a function of body weight is estimated using allometric equations from the US EPA Wildlife Exposure Factors Handbook (US EPA 1993).

$$\text{For mammals: } F = (0.621 * BW^{0.564}) / (1 - W)$$

Where:

F = food consumption (g wet weight/d),

BW = body weight (g), and

W = water content of food item (default values are 0.80 for most food items and 0.20 for seeds).

Susceptibility as a function of body weight is estimated using the following equations (US EPA 1993):

$$\text{For mammals: Adjusted LD}_{50} = \text{LD}_{50} * (\text{TW}/\text{AW})^{0.25}$$

$$\text{Adjusted NOAEL} = \text{NOAEL} * (\text{TW}/\text{AW})^{0.25}$$

Where:

Adjusted LD₅₀ = size-adjusted toxicity endpoint of the focal species (mg a.i./kg bw)

LD₅₀ = measured toxicity endpoint of a tested species (mg a.i./kg bw)

Adjusted NOAEL = size-adjusted toxicity endpoint of the focal species (mg a.i./kg/d)

NOAEL = measured toxicity endpoint of the tested species (mg a.i./kg/d)

AW = weight of the focal species (g)

TW = weight of the tested species (g)

The resulting risk estimates for mammals are shown in Table 8.8. The acute RQ is well below the listed species LOC of 0.1. Similarly, the chronic RQ is below the listed species LOC of 1.0; these values indicate minimal risk to raccoons.

Table 8.8. Imidacloprid risk estimation for mammals

| Species | Bodyweight (g) | Food Consumption (g) | Toxicity | Adjusted Toxicity | Estimated Exposure | RQ |
|-------------------|----------------|----------------------|----------------|-------------------|--------------------|--------|
| Raccoon – acute | 6000 | 419.7 | 424 mg/kg | 208.4 mg/kg | 0.10 mg/kg | 0.0004 |
| Raccoon - chronic | 6000 | 419.7 | 12.5 mg/kg/day | 6.14 mg/kg/day | 0.10 mg/kg/day | 0.016 |

8.1.2.3 Honey bees

In the review of the EUP for imidacloprid, EPA (2009) states: “*Acute toxicity studies with honeybees show that imidacloprid is very highly toxic to non-target insects (LD₅₀ = 0.0039 - 0.078 µg/bee). This is a concern for pollinators because imidacloprid is a systemic pesticide which has been shown to translocate into the nectar and pollen of crop plants grown from treated seed. Studies with ornamental plants have*

shown that imidacloprid may also translocate into plant parts when the chemical is applied to the soil around the base of the plants. In these studies with ornamentals, detectable residues were found in flowers and leaves as long as 540 days after application to the soil. However, under the current application, risks to bees should be low since it is an aquatic use and not near bee habitats.”

As the proposed use pattern and approved labels show, imidacloprid will be applied either to exposed mudflats at low tide or to water covering shellfish beds. There is no possibility that bees will be foraging over mudflats or over the water covering shellfish beds. Furthermore, shellfish beds are typically some distance from the mean high tide mark, due to the bathymetry of Willapa Bay and Grays Harbor. That is, there can be substantial distances between the water line at mean low tide and at mean high tide. In Willapa Bay at low tide, the tidal flats are exposed for distances of a mile (L. Turner, personal communication April 22, 2011). These distances will reduce the likelihood of drift from applications reaching areas where bees could be foraging or bee hives could be located.

8.1.2.4 Terrestrial plants

Imidacloprid is an insecticide and has low toxicity to plants. Furthermore, terrestrial plants are unlikely to be exposed to significant amounts of imidacloprid, due to the use pattern for control of burrowing shrimp in shellfish beds, as outlined above for birds, mammals, and bees.

8.1.2.5 Risk summary for terrestrial organisms

The assessment shows that exposures of amphibians, honey bees, and non-target terrestrial plants are likely to be very low, due to the use pattern of imidacloprid to control burrowing shrimp on shellfish beds. For the birds and mammals that might use the treated shellfish beds, and thus be exposed, a conservative assessment for direct effects shows that there is minimal acute or chronic risk. As to indirect effects, for example through the food chain, only small areas of Grays Harbor or Willapa Bay will be treated at one time, and the effects of imidacloprid have been shown to be minimal and transient (Section 6.4.7, Table 6.3).

8.1.3 Endangered and Threatened Species

8.1.3.1 Overview

According to FWS, 26 listed species are associated with the 3 counties (Grays Harbor, Pacific, and Wahkiakum) potentially affected by treatment. These species included 7 whales (Blue, finback, humpback, killer, Northern Pacific right, sei, and sperm), one species of sea lion (Steller's), three species of sea turtles (leatherback, loggerhead, green), and one species of plant (Marsh Sandwort *Arenaria paludicola*). These species were not considered any further because of their typical habitats, size, or taxonomy.

The results of the county-level overlap for species that will be considered for further analysis are shown in Table 8.9.

Table 8.9. Listed species and critical habitat occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA

| Species Common Name | Species Latin Name | Counties | Designated Critical Habitat in Willapa Bay or Grays Harbor |
|------------------------------|---|----------------------------------|--|
| Fish | | | |
| Bull Trout | <i>Salvelinus confluentis</i> | Grays Harbor, Pacific, Wahkiakum | Yes |
| Chinook Salmon | <i>Oncorhynchus</i> (=Salmo) <i>tshawytscha</i> | Pacific, Wahkiakum | No |
| Chum Salmon | <i>Oncorhynchus</i> (=Salmo) <i>keta</i> | Pacific, Wahkiakum | No |
| Sockeye Salmon | <i>Oncorhynchus</i> (=Salmo) <i>nerka</i> | Pacific, Wahkiakum | No |
| Coho Salmon | <i>Oncorhynchus</i> (=Salmo) <i>kisutch</i> | Pacific, Wahkiakum | No |
| Steelhead | <i>Oncorhynchus</i> (=Salmo) <i>mykiss</i> | Pacific, Wahkiakum | No |
| Green Sturgeon | <i>Acipenser medirostris</i> | Grays Harbor, Pacific, Wahkiakum | Yes |
| Pacific Eulachon | <i>Thaleichthys pacificus</i> | Grays Harbor, Pacific, Wahkiakum | No |
| Birds | | | |
| Marbled Murrelet | <i>Brachyramphus marmoratus</i> | Grays Harbor, Pacific, Wahkiakum | Yes |
| Northern Spotted Owl | <i>Strix occidentalis caurina</i> | Grays Harbor, Pacific, Wahkiakum | Yes |
| Short-tailed Albatross | <i>Phoebastria</i> (=Diomedea) <i>albatrus</i> | Grays Harbor, Pacific | No |
| Western Snowy Plover | <i>Charadrius alexandrinus nivosus</i> | Grays Harbor, Pacific | Yes |
| Insects | | | |
| Oregon Checkerspot Butterfly | <i>Speyeria zerene hippolyta</i> | Grays Harbor, Pacific | No |
| Mammals | | | |
| Columbia White-tailed Deer | <i>Odocoileus virginianus leucurus</i> | Wahkiakum | No |

The second step in the assessment was to evaluate the potential of imidacloprid to cause direct and indirect effects on the species, or to adversely alter their critical habitat. Species were examined with respect to their current listing status, species location at the county and sub-county level, species biology, and species habitat requirements in order to determine whether or not exposure to imidacloprid is of potential concern. Then, a potential for exposure conclusion was formulated. Conclusions, supporting comments, and references for each species evaluated are detailed below.

8.1.3.2 Species-specific findings

8.1.3.2.1 Fish

Direct Effects

Bull Trout *Salvelinus confluentis*

Chinook Salmon *Oncorhynchus* (=Salmo) *tshawytscha*

Chum Salmon *Oncorhynchus* (=Salmo) *keta*

Sockeye Salmon *Oncorhynchus* (=Salmo) *nerka*

Coho Salmon *Oncorhynchus* (=Salmo) *kistutch*

Steelhead *Oncorhynchus* (=Salmo) *mykiss*

Green Sturgeon *Acipenser medirostris*

Pacific Eulachon *Thaleichthys pacificus*

The screening level risk assessment, a worst case, showed that there is very low risk to fish. All RQs for fish are well below the endangered species LOC.

Indirect Effects

The potential indirect effects and adverse effects on primary constituent elements (PCEs) of critical habitat will be covered for each fish species in more detail below. Table 8.10 sets out the dietary habits of the listed fish that occur in Willapa Bay and Grays Harbor.

Table 8.10. Summary of diets of the listed fish occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA.

| Species Common Name | Diet and Source |
|---------------------|--|
| Bull Trout | Eats terrestrial and aquatic insects, macrozooplankton, mysids, and fish. Young feed heavily on aquatic insects. Adults feed principally on fish, but have also been known to eat other small vertebrates, including frogs, snakes, mice, ducklings, etc. (Moyle 1976). The amphidormous Coastal-Puget Sound DPS seems to prefer fish such as Pacific herring, surf smelt, and sandlance (FWS 2004; Proposed Critical Habitat Designation page 35770). |
| Chinook Salmon | In fresh water juveniles feed opportunistically on terrestrial and aquatic insects. In salt water they eat crustaceans as well as other bottom invertebrates. Adults eat mostly fishes (NatureServe 2010). |
| Chum Salmon | In fresh water juveniles feed on Diptera larvae, diatoms, and 48yclops; in salt water they feed on a variety of zoo- plankton. Adults feed on: polychaetes, pteropods, squid, crustacean larvae, copepods, amphipods, fish (Wydoski and Whitney 1979). |
| Sockeye Salmon | Young sockeye eat primarily planktonic crustaceans. At sea, young sockeye feed on zooplankton, small fishes and insects; as they grow they eat more fish (NatureServe 2010). |
| Coho Salmon | At sea, this salmon preys primarily on fish, but it will take invertebrates as well (NatureServe 2010). |
| Steelhead | In lakes, feeds mostly on bottom-dwelling invertebrates (e.g., aquatic insects, amphipods, worms, fish eggs, sometimes small fish) and plankton. In streams, feeds primarily on drift organisms. May ingest aquatic vegetation (probably for attached invertebrates). Diet changes seasonally. In the ocean, the diet consists of fishes and crustaceans (NatureServe 2010). |
| Green Sturgeon | Adults in the Sacramento-San Joaquin Delta are reported to feed on benthic invertebrates including shrimp, mollusks, amphipods, and even small fish (USFWS 2005a). |
| Pacific Eulachon | Eulachon larvae and juveniles eat phytoplankton, copepods, copepod eggs, mysids, barnacle larvae, and worm larvae. Adults eat zooplankton, such as copepods, euphausiids, malacostracans, and cumaceans (NMFS 2011). |

8.1.3.2.1.1 Bull Trout *Salvelinus confluentis*

There appears to be no documented evidence of occupancy of the bull trout in Willapa Bay and Grays Harbor (FWS 2004; Proposed Designation of Critical Habitat, p. 35768). Nonetheless, Grays Harbor and Pacific counties are mentioned in the Revised Designation of Critical Habitat, (FWS 2010a, p. 63938), so it will be assumed that bull trout could occur in the two bodies of water.

Indirect Effects

Bull trout are stated to eat primarily fish (FWS 2004; Proposed Critical Habitat Designation, p. 35770). It is unlikely that use of imidacloprid would result in reductions in fish populations. All RQs are well below the listed species LOC for fish (see http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm)

Adverse Habitat Modification

There are 5 PCEs of Critical Habitat for the Bull Trout: (1) space for individual and population growth and for normal behavior; (2) food, water, air, light, minerals, or other nutritional or physiological requirements; (3) cover or shelter; (4) sites for breeding, reproduction, or rearing (or development) of offspring; and (5) habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species (FWS 2010a; Revised Critical Habitat Designation, p. 63929). Of these 5 PCEs, it is believed that imidacloprid has the potential to affect only PCE 2. As mentioned above, there seems to be little possibility that imidacloprid use could reduce populations of fish, so there does not appear to be adverse modification of PCE 2.

Conclusion

There is no likelihood of indirect effects or adverse habitat modification.

8.1.3.2.1.2 Chinook Salmon *Oncorhynchus* (=Salmo) *tshawtscha*

Indirect Effects

Chinook salmon juveniles in saltwater are said to eat a variety of crustaceans and other bottom-dwelling invertebrates. Adults are said to feed primarily on fish. It is therefore possible that reductions in crustaceans and other bottom-dwelling invertebrate populations due to application of imidacloprid reduce the food supply available and cause an indirect effect. It is suggested that such an effect would be related to the crustacean and bottom-dwelling invertebrate species potentially affected by imidacloprid, and by the extent of any effects within Willapa Bay and Grays Harbor. The description of the crustaceans and bottom-dwelling invertebrates eaten by juvenile Chinook salmon indicates that it is a generalist, and not focused on one or a few species. The extent of the potential effects on the total invertebrate food supply will depend on the numbers of acres of tidal mudflat treated each year, and Chinook salmon use of that area. It is anticipated that any potential effects on crustaceans and bottom-dwelling invertebrates will be transient. So the questions that must be addressed are: How much of a reduction in the crustacean and bottom-dwelling invertebrate food supply will cause indirect effects?; and; How much (what proportion) of Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge mudflat areas of both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it is very unlikely that there could be a reduction in the available crustacean and bottom-dwelling invertebrate food supply such that it would cause an indirect effect.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for Chinook salmon.

(http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm).

Conclusion

There is a low likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.1.3 Chum Salmon *Oncorhynchus* (=Salmo) *keta*

Indirect Effects

Chum salmon adults feed on polychaetes, pteropods, squid, crustacean larvae, copepods, amphipods, and fish. It is therefore possible that reductions in these populations due to application of imidacloprid could reduce the food supply available and cause an indirect effect. It is suggested that such an effect would be related to the saltwater invertebrate species potentially affected by imidacloprid, and by the extent of any effects within Willapa Bay and Grays Harbor. The description of the saltwater invertebrates eaten by adult Chum salmon indicates that it is a generalist, and not focused on one or a few species. The extent of the potential effects on the total invertebrate food supply will depend on the numbers of acres of tidal mudflat treated each year, and Chum salmon use of that area. It is anticipated that any potential effects on

crustaceans and bottom-dwelling invertebrates will be transient. So the questions that must be answered are: How much of a reduction in the crustacean and bottom-dwelling invertebrate food supply will cause indirect effects?; and; How much (what proportion) of Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge areas of mudflats in both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it does not appear that there could be a reduction in the available invertebrate food supply such that it would cause an indirect effect.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for Chum salmon (http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm).

Conclusion

There is a low likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.1.4 Sockeye Salmon *Oncorhynchus* (=Salmo) nerka

Indirect Effects

Young sockeye eat primarily planktonic crustaceans. At sea, young sockeye feed on zooplankton, small fishes and invertebrates; as they grow they eat more fish. It could therefore happen that reductions in saltwater invertebrate populations due to application of imidacloprid could possibly reduce the food supply available and cause an indirect effect. It is suggested that such a potential effect would be related to the saltwater invertebrate species affected by imidacloprid, and by the extent of potential effects within Willapa Bay and Grays Harbor. The description of the saltwater invertebrates eaten by adult sockeye salmon indicates that it is a generalist, and not focused on one or a few species. The extent of the potential effects on the total invertebrate food supply will depend on the numbers of acres of tidal mudflat treated each year, and sockeye salmon use of that area. It is anticipated that the potential effects on crustaceans and bottom-dwelling invertebrates will be transient, at least on a yearly basis. So the questions that must be answered are: how much of a reduction in the crustacean and bottom-dwelling invertebrate food supply will cause indirect effects?, and; How much (what proportion) of Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge areas of both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it does not appear that there could be a reduction in the available crustaceans and bottom-dwelling invertebrate food supply such that it would cause an indirect effect.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for sockeye salmon (http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm).

Conclusion

There is a low likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.1.5 Coho Salmon *Oncorhynchus* (=Salmo) kisutch

Indirect Effects

At sea, coho salmon prey primarily on other fishes, but they will also take invertebrates. Reductions in fish populations due to the use of imidacloprid are unlikely. Potential reductions in saltwater invertebrate populations due to application of imidacloprid could reduce the food supply available and cause an indirect effect. It is suggested that such a potential effect would be related to the saltwater invertebrate species affected by imidacloprid, and by the extent of potential effects within Willapa Bay and Grays Harbor. The description of the saltwater invertebrates eaten by coho salmon indicates that it is a

generalist, and not focused on one or a few species. The extent of the potential effects on the total invertebrate food supply will depend on the numbers of acres of tidal mudflat treated each year, and coho salmon use of that area. It is anticipated that the any potential effects on invertebrates will be transient. So the questions that must be answered are: how much of a reduction in the invertebrate food supply will cause indirect effects?, and; How much (what proportion) of Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge areas of both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it does not appear that there could be a reduction in the available invertebrate food supply such that it would cause an indirect effect. The coho also is likely to concentrate more on fish, which are its preferred food items.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for coho salmon

(http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm).

Conclusion

There is a low likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.1.6 Steelhead *Oncorhynchus* (=Salmo) mykiss

Indirect Effects

In the ocean, the diet consists of fishes and crustaceans. It is therefore possible that potential reductions in crustacean populations due to application of imidacloprid could reduce the food supply available and cause an indirect effect. It is suggested that such a possible effect would be related to the crustacean species potentially affected by imidacloprid, and by the extent of potential effects within Willapa Bay and Grays Harbor. The description of the crustaceans eaten by steelhead indicates that it is a generalist, and not focused on one or a few species. The extent of any potential effects on the total crustacean food supply will depend on the numbers of acres of tidal mudflat treated each year, and steelhead use of that area. It is anticipated that the effects on crustaceans will be transient. So the questions that must be answered are: How much of a reduction in the crustacean food supply will cause indirect effects?, and; How much (what proportion) of Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge areas of both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it does not appear that there could be a reduction in the available crustaceans and bottom-dwelling invertebrate food supply such that it would cause an indirect effect.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for steelhead

(http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.htm).

Conclusion

There is a low likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.1.7 Green Sturgeon *Acipenser medirostris*

Indirect Effects

Adults in the Sacramento-San Joaquin Delta are reported to feed on benthic invertebrates including shrimp, mollusks, amphipods, and even small fish. In the ocean, the diet consists of fishes and crustaceans. It is therefore possible that reductions in crustacean populations due to application of imidacloprid could possibly reduce the food supply available and cause an indirect effect. It is suggested that such a potential effect would be related to the crustacean species possibly affected by imidacloprid,

and by the extent of potential effects within Willapa Bay and Grays Harbor. The description of the crustaceans eaten by sturgeon indicates that it is a generalist, and not focused on one or a few species. The extent of the potential effects on the total crustacean food supply will depend on the numbers of acres of tidal mudflat treated each year, and sturgeon use of that area. It is anticipated that the potential effects on crustaceans will be transient. Relevant questions are: how much of a reduction in the crustacean food supply will cause indirect effects, and how much area in Willapa Bay or Grays Harbor would have to be treated to cause this reduction? Given the huge areas of mudflats in both Willapa Bay and Grays Harbor, and the relatively small areas that have been treated with carbaryl in the past, it does not appear that there could be a reduction in the available crustacean food supply such that it would cause an indirect effect.

Adverse Habitat Modification

The essential features of Critical Habitat for the green sturgeon in estuarine areas include: (1) Food resources; (2) Water flow; (3) Water quality; (4) Migratory corridor; (5) Water depth; (6) Sediment quality (NMFS 2009; Final Critical Habitat Designation, p. 52324). Of these 5 PCEs, it is believed that imidacloprid has the potential to affect only PCE 1, Food resources. As mentioned above, it is potentially possible that imidacloprid use could reduce populations of crustaceans, both at the species level and at the overall population density level within the treated areas or immediately adjacent to them. If the potential reductions were severe enough, over a wide area, they might constitute an adverse habitat modification. Because field tests have demonstrated that application of imidacloprid does not adversely affect all crustaceans in a treated area, there would be prey species available. Because carbaryl was applied to very small areas of Willapa Bay and Grays Harbor, and because green sturgeons are highly mobile (Moser and Lindley 2007), they are likely to seek crustaceans in areas of the estuaries that have not been treated with imidacloprid if the abundance of prey in treated areas is not sufficient for foraging. NMFS scientists have raised concerns about potential effects of reduced ghost shrimp populations on the potential for green sturgeon to optimize their growth potential in Willapa Bay in the summer (Moser and Lindley 2007, p. 243). Nonetheless, other scientists (Dumbauld et al. 2008, p. 283), considered it unlikely that current burrowing shrimp abundance is a limiting factor for threatened green sturgeon stocks, even when it is necessary to control ghost shrimp in order to raise shellfish.

Conclusion

There is a low likelihood of indirect effects or adverse habitat modification.

8.1.3.2.1.8 Pacific Eulachon *Thaleichthys pacificus*

Indirect Effects

Pacific Eulachon eat a variety of invertebrates, such as copepods, mysids, barnacle larvae, worm larvae, euphausiids, malacostracans, and cumaceans (NMFS 2011; Final Critical Habitat Designation, p. 65326). However, the eulachon spend 95 to 98% of their lives at sea, and in the sea they forage near the ocean bottom at depths of 20 to 150 meters (NMFS 2011; Final Critical Habitat Designation, p. 65325). Furthermore, spawning adults do not feed (NMFS 2011; Final Critical Habitat Designation, p. 65326), and they do not spawn in estuarine waters. It is thus very unlikely that the potential transient reductions in invertebrates on small areas of Willapa Bay and Grays Harbor, due to imidacloprid treatments, could cause indirect effects on the eulachon.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for Pacific Eulachon (NMFS 2011; Final Critical Habitat Designation, Table 1, pp. 65339-65340).

Conclusion

There is no likelihood of indirect effects or adverse habitat modification.

8.1.3.2.2 Birds

Direct Effects

Marbled Murrelet *Brachyramphus marmoratus*

Northern Spotted Owl *Strix occidentalis caurina*

Short-tailed Albatross *Phoebastria (=Diomedea) albatrus*

Western Snowy Plover *Charadrius alexandrinus nivosus*

The screening level risk assessment, a worst case, showed that there is very low risk to birds. All RQs for birds are well below the endangered species LOC.

Indirect Effects

The potential indirect effects and adverse effects on primary constituent elements (PCEs) of critical habitat will be covered for each bird species in more detail below. Table 8.10 sets out the dietary habits of the listed birds that occur in Willapa Bay and Grays Harbor.

Table 8.11. Summary of diets of the listed birds occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA.

| Species Common Name | Diet and Source |
|------------------------|--|
| Marbled Murrelet | Eats fishes (sandlance, capelin, herring, etc.), crustaceans (mysids, euphausiids), and mollusks. In the Pacific Northwest, the main fish prey items are the Pacific sand lance (<i>Ammodytes hexapterus</i>), Pacific herring (<i>Clupea harengus</i>), northern anchovy (<i>Engraulis mordax</i>), and smelts (Osmeridae) (FWS 1997; Recovery Plan, p. 22). Adults are thought to feed on marine invertebrates and smaller size classes of fish that are fed to chicks (FWS 1997; Recovery Plan, p. 23). |
| Northern Spotted Owl | Eats mammals, birds, reptiles, and insects. The diet varies geographically and by forest type, although small mammals typically make up the bulk of food items. Flying squirrels are the most important food item in Douglas-fir and western hemlock forests in WA and OR. Dusky-footed wood rats are the predominant food item in OR Klamath, CA Klamath, and CA Coastal Provinces. Other important, less-dominant prey include deer mice, tree voles, red-backed voles, gophers, snowshoe hare, bushy-tailed wood rats, birds, and insects (FWS 2008b, 2010b). |
| Short-tailed Albatross | Feeds on squid, fish, flying fish eggs, shrimp, and other crustaceans. There is currently no information on seasonal, habitat, or environmental effects on choice of diet (FWS 1998; Proposed Listing Rule, 11-02-1998, p. 58695; FWS 2000; Final Listing Rule 7-31-00, p. 46647). |
| Western Snowy Plover | Feeds on marine invertebrates from the intertidal zone or higher on beaches and from the edges of salt water bodies. Also eats terrestrial invertebrates, such as flies and beetles, and small fish (FWS 2007; Recovery Plan, p 17-18). |

8.1.3.2.2.1 Marbled murrelet *Brachyramphus marmoratus*

Indirect Effects

The marbled murrelet has a unique life history strategy: it uses nearshore marine waters for foraging, but it flies inland and nests on large limbs of mature conifers, generally returning to the nearshore waters to forage (FWS 1997; Recovery Plan, p. 18). The species has occasionally been observed foraging in inland lakes in British Columbia and Washington (FWS 1997; Recovery Plan, p. 23). Nesting areas are forest stands with old-growth characteristics, usually within 50 miles of the coast (FWS 1997; Recovery Plan, p. 32). Nests have been observed in Douglas fir, Alaska yellow cedar, western hemlock, Sitka spruce, mountain hemlock, coast redwood, and western red cedar; the trees ranged in height from 16.5 to 86.5 meters (FWS 1997; Recovery Plan, p. 35). Critical habitat for the species has been designated (FWS 1996).

It is unlikely that imidacloprid would reach either the near shore foraging habitat or the mature growth nesting habitat of the murrelet in amounts that would result in significant residues on its food items. Thus, the proposed use of imidacloprid is unlikely to have indirect effects on the marbled murrelet.

Adverse Habitat Modification

The marbled murrelet's primary constituent elements are (1) forested stands containing trees with potential nesting platforms, and (2) the surrounding forested areas within 0.5 mi (0.8 km) of these stands with a canopy height of at least one-half the site-potential tree height. Imidacloprid is not expected to reduce the populations of fish upon which the murrelet feeds, or to adversely affect PCEs of its critical habitat.

Conclusion

There is a low likelihood of indirect effects, and no likelihood of adverse habitat modification.

8.1.3.2.2.2 Northern spotted owl *Strix occidentalis caurina*

Indirect Effects

The northern spotted owl generally relies on mature and old-growth forests because these habitats contain the structures and characteristics that it requires for nesting, roosting, and foraging (FWS 2008a; Recovery Plan, p. vii). The species has been observed in Douglas-fir, western hemlock, grand fir, white fir, ponderosa pine, Shasta red fir, mixed evergreen, mixed conifer hardwood (Klamath montane, Marin County), and redwood forests; in addition, owls in Marin County, California use Bishop pine forests and mixed evergreen-deciduous hardwood forests (FWS 2008a; Recovery Plan, p. 50). Critical habitat has been designated for the species (FWS 2008b).

It is unlikely that imidacloprid would reach the mature and old-growth forest habitats that the species utilizes in amounts that would directly affect the owl. Due to the large home range, the mature and old-growth forest habitat, and the types and variety of animal food items the owl takes, it is unlikely that imidacloprid will cause indirect effects.

Adverse Habitat Modification

The northern spotted owl's primary constituent elements are (1) forest types that support the northern spotted owl geographic range, which are primarily Sitka spruce, western hemlock, mixed conifer and mixed evergreen, and various firs; and (2) nesting, roosting, and foraging habitats. Imidacloprid is not expected to reduce the populations of vertebrates on which the owl feeds, or to adversely affect PCEs of its critical habitat.

Conclusion

There is no likelihood of indirect effects, and no likelihood of adverse habitat modification.

8.1.3.2.2.3 Short-tailed albatross *Phoebastria (=Diomedea) albatrus*

Indirect Effects

The short-tailed albatross is also called the "coastal albatross"; it is usually observed within 6 miles of shore and occasionally within 3 miles of shore (FWS 1998; Proposed Listing Rule, 11-02-1998, p. 58695). These regions are characterized by upwelling and high productivity (FWS 1998; Proposed Listing Rule, 11-02-1998, p. 58695). Most records along Oregon and Washington are from satellite tracking records. They typically feed along the break in the continental shelf along OR and WA, about 10 miles out, though they do feed in "Astoria Canyon off the mouth of the Columbia River (R. Suryan, personal communication). Critical habitat has not been designated for the species.

It is unlikely that imidacloprid would reach the near shore habitat of the species in amounts that would result in significant residues on its food items, causing indirect effects. The occurrence of the species offshore and its diet of pelagic organisms make it unlikely that imidacloprid affects it directly. Also, the assessment for Heerman's gull shows that risk to fish-eating birds is low (NatureServe 2010). Imidacloprid is not expected to reduce the populations of fish upon which the albatross feeds.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for the short-tailed albatross (http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.html).

Conclusion

There is no likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.2.4 Western snowy plover *Charadrius alexandrinus nivosus*

Indirect Effects

The Pacific coast population of the western snowy plover nests within 50 miles of the Pacific mainland coast of the US from southern Washington State south to Baja California (FWS 2007; Recovery Plan, p. 1). It breeds primarily above the high tide line on coastal beaches, sand spits, dune-backed beaches, sparsely-vegetated dunes, beaches at creek and river mouths, and salt pans at lagoons and estuaries. Less commonly, it nests on bluff-backed beaches, dredged material disposal sites, salt pond levees, dry salt ponds, and river bars. In either case, vegetation is usually sparse or absent (FWS 2007; Recovery Plan, p. 11). The plover winters on many of the beaches it uses for nesting; but it also winters on beaches where it does not nest, in man-made salt ponds, and on estuarine sand and mud flats (FWS 2007; Recovery Plan, p. vi). It is unlikely that imidacloprid would reach the beach and sand habitats that the plover uses for breeding and wintering in amounts that would result in significant residues on its food items. And, even the worst case assessment for these residues shows that the endangered species LOC is not exceeded. Critical habitat has been designated for the species (FWS 2005b).

Adverse Habitat Modification

The western snowy plover's primary constituent elements are (1) areas that are below heavily vegetated areas or developed areas and above the daily high tides; (2) shoreline habitat areas for feeding, that are between the annual low tide or low-water flow and annual high tide or high-water flow; (3) surf- or water-deposited organic debris, such as seaweed or driftwood; and (4) minimal disturbance from the presence of humans, pets, vehicles, or human-attracted predators. Imidacloprid is not expected to reduce the populations of invertebrates upon which the plover feeds, or to adversely affect PCEs of its critical habitat.

Conclusion

There is a low likelihood of indirect effects, and a low likelihood of adverse habitat modification.

8.1.3.2.3 Insects

8.1.3.2.3.1 Oregon checkerspot (silverspot) butterfly *Speyeria zerene hippolyta*

Indirect Effects

Invasion by exotic species, natural succession, fire suppression, and land development has resulted in loss or modification of habitat (FWS 2001; Recovery Plan page iii). Other threats include off-road vehicles, grazing, erosion, road kill, pesticides, and collectors.

A project is in progress to re-introduce the early blue violet, but that project is in its early stages (Personal communication, William Ritchie to Larry Turner 4/11/11). When (and if) the butterfly is re-introduced, it

will be in 2 areas. The first is in the vicinity of Loomis Lake, which is separated from Willapa Bay by a considerable distance (approximately 1.0 mile). The area between Loomis Lake and the Bay has substantial tall vegetation that would intercept any potential drift that would result from applications of imidacloprid. The second area is in the Tarlatt Unit (South) of the Willapa Bay National Refuge, which is south and east of the southernmost extent of the Bay. It is also separated from the Bay. Therefore, direct effects are unlikely. Also, it is not likely that mudflats near Loomis Lake or the Tarlatt Unit would ever be treated with imidacloprid. This is because those mudflats would be used only for seed oysters, for which burrowing shrimp are not a threat. The area is not suited for “fattening” oysters because the tidal flow is not sufficient to bring in adequate food.

Larvae feed primarily on early blue violets; large stands of these are needed. Densities should be 25+ per square yard (FWS 2001; Recovery Plan, p. 13). The larvae will also feed on other species in the genus *Viola*. Imidacloprid, an insecticide, is not expected to reduce the populations of plants upon which the silverspot feeds.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for Oregon checkerspot butterfly (http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.html).

Conclusion

There is no likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.2.4 Mammals

8.1.3.2.4.1 Columbia white-tailed deer *Idocoileus virginianus leucurus*

Indirect Effects

The Columbia River population occurs along the lower river from Wallace Island (river mile 50) downstream to Karlson Island (river mile 32) (Recovery Plan FWS 1983, p. 5). The deer inhabits the lowlands or tidelands that are not more than 3 meters above sea level (FWS 1983; Recovery Plan, p. 9-10). The vegetation is a dense, tall shrub or tree community of Sitka spruce (*Picea sitchensis*), dogwood (*Cornus stolonifera*), cottonwood (*Populus trichocarpa*), red alder (*Alnus rubra*), and willow (*Salix* spp.). Most of the bottomlands have been cleared of brush and trees and have grasses or forbs. Species of *Rubus*, *Juncus*, *Carex*, *Rosa*, *Sambucus*, and *Symphoricarpos* are commonly used as food and cover by the deer (FWS 1983; Recovery Plan, p. 10).

The typical habitat of the Columbia white-tailed deer is quite different from the mud flats where imidacloprid would be applied, the cover and food items the deer needs will not be present, and given the fact that the Columbia River population is many (> 50) miles from Willapa Bay and Grays Harbor, indirect effects resulting from exposure to imidacloprid are not likely. Imidacloprid is not expected to affect the populations of plants upon which the deer feeds.

Adverse Habitat Modification

Willapa Bay and Grays Harbor contain no designated Critical Habitat for the Columbia white-tailed deer. (http://www.wsdot.wa.gov/Environment/Biology/bio_noaa.html)

Conclusion

There is no likelihood of indirect effects, and no designated Critical Habitat in Willapa Bay or Grays Harbor.

8.1.3.3 Risk summary for endangered species

The overall conclusions for the 14 federally listed species are given in Table 8.12. Imidacloprid use in Willapa Bay and Grays Harbor will have no direct effects on any of these species. There will be no indirect effects on bull trout, Pacific eulachon, northern spotted owl, short-tailed albatross, Oregon checkerspot butterfly, or Columbia white-tailed deer. Imidacloprid is not likely to cause adverse indirect effects on the other species. Critical Habitat has been designated in Willapa Bay and Grays Harbor for bull trout, green sturgeon, marbled murrelet, northern spotted owl, and western snowy plover. Imidacloprid will not cause habitat modification for bull trout, marbled murrelet, and northern spotted owl, and is not likely to cause adverse habitat modification for the green sturgeon and western snowy plover.

Table 8.12. Summary of conclusions for listed species, indirect effects and critical habitat occurring in Grays Harbor, Pacific, and Wahkiakum Counties, WA.

| Species Common Name | Direct Effects | Indirect Effects | Critical Habitat Designated in Willapa Bay or Grays Harbor | Adverse Habitat Modification |
|-------------------------------|----------------|-------------------|--|------------------------------|
| Fish | | | | |
| Trout, bull | No | No | Yes | No |
| Salmon, chinook | No | NLAA ¹ | No | -- |
| Salmon, chum | No | NLAA | No | -- |
| Salmon, sockeye | No | NLAA | No | -- |
| Salmon, coho | No | NLAA | No | -- |
| Steelhead | No | NLAA | No | -- |
| Sturgeon, green | No | NLAA | Yes | NLAA |
| Eulachon, Pacific | No | No | No | -- |
| Birds | | | | |
| Murrelet, marbled | No | NLAA | Yes | No |
| Owl, Northern spotted | No | No | Yes | No |
| Albatross, short-tailed | No | No | No | -- |
| Plover, Western snowy | No | NLAA | Yes | NLAA |
| Insects | | | | |
| Butterfly, Oregon checkerspot | No | No | No | -- |
| Mammals | | | | |
| Deer, Columbia white-tailed | No | No | No | -- |

¹NLAA = Not Likely to Adversely Affect

8.2 Effects on water quality

There are no data available to assess the effects of imidacloprid applications to water quality parameters such as pH, dissolved oxygen, nitrate, nitrite, and ammonia production, and the release of phosphates. However, no effects are expected, based on the chemical and physical properties of the product and the expected concentrations and frequencies of its use in Willapa Bay and Grays Harbor.

8.3 Effects from interactions with other pesticides

Imidacloprid does not interact strongly with any known pesticides, and exhibits no synergistic tendencies (see Section 9.3.2.3).

8.4 Effects on pristine and contaminated sites

No data are available. Presumably there would be no use in contaminated sites, since oysters grown for food would not be raised on such sites. Toxicity data are generated in what could be considered pristine

waters and should therefore apply to pristine sites. However, cultivated oyster beds would not be considered a “pristine site” since it is a managed environment.

8.5 Indirect effects

Indirect effects are addressed and organized by species in Section 8.1.

8.6 Impacts of multiple applications

The effects of multiple applications of imidacloprid at the proposed treatment sites were not studied. Since both formulation labels restrict application at a given site to no more than one treatment annually and imidacloprid residues are shown to dissipate rapidly and therefore highly unlikely to persist after one year, there was no need to consider such effects.

8.7 Impacts on terrestrial organisms and environments

Impacts on terrestrial biota are addressed in Section 8.1.2.

8.8 Impacts on wetlands other than target application sites

Areas adjacent to shellfish beds treated with imidacloprid are not expected to receive sufficient exposure to cause ecologically significant effects.

8.9 Uncertainty analysis

All risk assessments are subject to numerous sources of uncertainty in estimation of both exposure and ecological effects. Often, exposure estimates are based on generic environmental fate models that may or may not adequately reflect the conditions in a particular use site, and on toxicity data for surrogate species that may or may not be representative of the biota of a particular receiving ecosystem. This risk assessment of imidacloprid is exceptional in that it is based on residue measurements in the actual use site under conditions approximating commercial use, and on toxicity data that include a large number of species endemic to Willapa Bay and Grays Harbor. Laboratory data suggest, and field observations confirm, that exposure and effects on the most sensitive taxa, such as shrimp and Dungeness Crab, will be brief and limited to the treatment area.

8.10 Additional needs for information

8.10.1 Soil and sediment

There is a significant database available for imidacloprid associated with registration packages for crop uses. This information includes a full battery of recent laboratory and field studies on soil metabolism and dissipation in soils. In addition, work has been completed on aquatic sediments under various conditions in the laboratory. Initial field measurements associated with the proposed use over shell beds for control of burrowing shrimp have been completed. These preliminary studies support the importance of environmental conditions to the rapid dissipation of this product. Further studies under actual use conditions may provide additional insight into the importance of physical versus metabolic factors in dissipation within the estuarine environment, but would not be expected to affect the conclusions of this risk assessment.

8.10.2 Water

Laboratory studies designed to support crop registrations show that photolysis and microbial degradation are the key factors in aquatic dissipation. Initial work on aquatic uses for control of burrowing shrimp shows rapid compound dissipation in water, but does not provide information on the relative importance

of each environmental factor in this process. Additional work on photolysis, metabolism and physical factors under field conditions in the estuary may provide this information, which in turn provides a more detailed understanding of processes. However, it is unlikely that such elucidation would impact the results of this risk assessment.

8.10.3 Plants

Testing has been conducted on several indicator plant species showing that imidacloprid exhibits low toxicity to terrestrial and aquatic plants. This is supported by field information indicating no effects on eelgrasses on treated shell beds. Based on targeted applications, it is likely that exposure to other plants will be negligible. Therefore, it is not expected that additional studies on plants would provide any additional data meaningful to the risk assessment.

8.10.4 Acute toxicity studies

There is a substantial database on the acute toxicity of imidacloprid to terrestrial and aquatic indicator species associated with crop use registrations. In addition, toxicity studies have been conducted on numerous species endemic to the proposed estuarine use areas. This complete data set provides a substantial basis to estimate potential impact for the proposed uses. While additional studies on individual species endemic to the treatment area could be conducted, they would not be expected to produce values outlying those used for this assessment.

8.10.5 Chronic toxicity studies

As with the acute toxicity database, there are numerous studies conducted on the chronic toxicity of imidacloprid to indicator terrestrial and aquatic species. As part of this previous work, estuarine species have been tested in the laboratory. Based on the rapid dissipation after application in the estuarine environment, and the fact that treatment is infrequent and limited, it is not expected that chronic toxicity to endemic species requires further consideration or testing.

8.11 Mitigation measures

There does not appear to be a need to evaluate the impact or efficiency of additional mitigation efforts. Field studies to date demonstrate that there is limited on-site impact to non-target aquatic invertebrates, and that this impact is transient. The use of efficient and accurate application methods over treated shell beds will mitigate impacts beyond the targeted areas. The strict specification on the accepted labeling, of rotating applications at least a year apart, will limit any effects to temporary and transient events.

9. Human Health Effects

9.1 Objective

The Willapa Bay/Grays Harbor Oyster Growers Association (WGHOGA) contracted with Compliance Services International (CSI) to perform a risk assessment of imidacloprid use to control burrowing shrimp on oyster beds in Willapa Bay and Grays Harbor.

The purpose of this section is to provide the most recent health information concerning the potential risks to public health associated with imidacloprid in oyster pest control. This information will assist WGHOGA in making decisions regarding imidacloprid use and will support Washington Department of Ecology risk assessment needs.

The objectives of this section are to: (1) develop a public health risk assessment for imidacloprid as it applies to use of the product for burrowing shrimp control; (2) provide an overview of epidemiology and carcinogenicity of imidacloprid; and (3) present the information in a qualitative and quantitative manner that permits direct comparison of the estimated exposure concentrations with concentrations that are expected to protect public health.

9.2 Information compilation

Human health effects data pertaining to the active ingredient were primarily obtained from published EPA reports. These included notices published in the Federal Register, as well as summaries by Environmental Protection Agency (EPA) Health Effects Division (HED) and Environmental Fate and Effects Division (EFED) that are available on the imidacloprid Registration Review docket, including HED's Human Health Assessment Scoping Document in Support of Registration Review, EFED's New Use Drinking Water Assessment for Imidacloprid on Peanuts, Soybeans and IR-4 Registration for Crop Group 13A: Caneberries, HED's Response to Comments on Human-Health Assessment Scoping Document in Support of Registration Review (OPP Docket# EPA-HQ-OPP-2008-0884), HED's Updated Review of Imidacloprid Incident Reports and other related documents. Data were secondarily obtained from the European Food Safety Authority (EFSA) 2011 imidacloprid assessment report and 2006 draft assessment report. Other sources included a risk assessment submitted to the United States Department of Agriculture (USDA) Forest Service (Anatra-Cordone and Durkin, 2005), a risk characterization document prepared by California's Department of Pesticide Regulation (CEPA-DPR 2006), and miscellaneous published articles.

The toxicity value for each endpoint and its corresponding pathway was examined. The latest available new tolerance assessment on imidacloprid, available from the Federal Register, was used to identify EPA's toxicity ratings and the studies justifying its risk management decisions. The details of these and related studies—notably the findings related to prominent clinical symptoms and calculated toxicity values and no and lowest observable adverse effect levels, (LD₅₀'s, NOAELs and LOAELs)—were obtained from the EFSA 2006 document and are here discussed and catalogued. Finally, the reference doses (RfDs) for each endpoint were examined using the human health scoping document and the Federal Register notice on the establishment of new tolerances.

Some data pertaining to imidacloprid exposure relative to the study site were requested and obtained from WGHOGA, Washington State Department of Ecology (WDOE), and scientific literature.

9.3 Toxicology information and assessment

The WGHOGA has registered two formulations of imidacloprid (Protector 2F and Proctor 0.5G) for use in controlling two indigenous species of burrowing shrimp that severely impact oyster production in the Willapa Bay and Grays Harbor estuaries: ghost shrimp *Neotrypaea californiensis* and mud shrimp (*Upogebia pugettensis*). This use pattern described by draft labeling (Appendices C and D) will be evaluated in light of the toxicity data reviewed here.

The effects of imidacloprid on human health are deduced primarily from the manufacturer's *in vivo* studies of its effects on rats, mice, rabbits, and dogs. Such tests are performed under Good Laboratory Practice Standards (GLP, #40 CFR 160) and follow OPPTS Series 870 (Health Effects) harmonized test guidelines. These tests—in concert with exposure assessments—assure that public health will not be unduly at risk when this compound is used according to label instructions.

In toxicity scenarios where imidacloprid is expected to produce or has demonstrated variables overt of toxicity, multiple dose levels and sometimes repeated studies are used to establish reliable endpoints, and the resulting reported effects are compared in the decision making process. In scenarios where

imidacloprid effects on sensitive species appear to be negligible, EPA testing guidelines allow the manufacturer to submit a single “limit dose” test to show that even an exorbitant dose will not produce adverse effects in the test species.

There are no local conditions present to suggest that EPA’s conclusions of imidacloprid’s toxicity to humans in general are inappropriate for evaluating risk associated with use of imidacloprid as a result of its use on the proposed treatment sites. Furthermore, in granting the proposed registration and setting a tolerance for imidacloprid in shellfish, EPA has conducted its own risk assessment on this registration action.

9.3.1 Acute

The acute toxicity of imidacloprid has been studied in rats, mice, and rabbits. Depending on the route of exposure, acute toxicity ranges from EPA Category II to IV, with oral toxicity being the trigger for Category II labeling and warning statements. Information on acute toxicity is very consistent and there are no unusual outlying data points. Data relevant to expected potential routes of exposure that may be encountered in an acute situation, such as accidental spills or mishandling or accidents during application, are reviewed below. Acute data are also relevant for comparing acutely toxic doses to those concentrations that may arise in air, water or food as a result of the labeled use of the product. Table 9.1 summarizes the acute toxicity studies discussed below.

Table 9.1 Summary of Imidacloprid Acute Toxicity Studies

| Test Type | Species | IMI Purity % | NOAE L (mg/kg) | LOAEL (mg/kg) | LLD (mg/kg) | LD ₅₀ (mg/kg) | Reference |
|------------|---------|--------------|----------------|---------------|-------------|--------------------------|------------------|
| Oral | Rat | 94.2 | 50 | 100 | 400 | 424 | Bomann 1989a |
| Oral | Rat | 96.0 | 50 | 200 | 350 | 642 | Bomann 1991a |
| Oral | Rat | 94.3 | 200 | 300 | 300 | 379 | Bomann 1991b |
| Oral | Mouse | 94.2 | 10 | 71 | 100 | 131 | Bomann 1989b |
| Inhalation | Rat | 95.3 | 1220 | 2577 | - | - | Pauluhn 1988a |
| Dermal | Rat | 94.2 | > 5000 | - | - | - | Kroetlinger 1989 |

9.3.1.1 Oral

According to the EPA, imidacloprid has a moderate acute oral toxicity and is classified a Category II oral toxicant. In general, the rating for this endpoint is determined from a battery of acute (single-dose) studies. However, EPA based its rating for imidacloprid on a neurotoxicity study by Sheets and Hamilton (1994a) as a conservative approach to expressing acute toxicity. This study noted a lower single-dose effect level and thus was selected by EPA as the acute oral toxicity reference.

The neurotoxicity study found that the nervous system is the primary target organ of imidacloprid and effects include decreased motor activities, tremors, gait abnormalities, increased righting reflex impairments and body temperature, and decreased number of rears and response to stimuli.

The EPA determined this study’s LOAEL to be 42 mg/kg/day, based on decreased motor and locomotor activities in females. The corresponding uncertainty factor was judged to be 300 based on interspecies variation (x10), intraspecies variation (x10), and the use of the LOAEL instead of the NOAEL (x3).

Three acute toxicity studies by Bomann (1989a, 1991a, 1991b) using technical grade (94.2% - 96.0%) imidacloprid formulated in Cremophor® EL/demineralized water (2% v/v) provide general support for the neurotoxicity findings described above. These data suggest that the small differences in technical grade

imidacloprid purity do not strongly affect toxicity results. This is true of all studies reported in this document; hence differences in reported values of technical grade purity are treated as negligible.

A parallel study to those above (Bomann, 1989b) dosed mice using technical grade (94.2%) imidacloprid formulated in Cremophor® EL/demineralized water (2% v/v) and found similar clinical symptoms: apathy and labored breathing at low doses, decreased motility, tremors, and staggering gait and severe trembling at higher doses. Deaths were observed in 20% of males at 100 mg/kg/day and 20% of females at 120 mg/kg/day. Toxicity was evident within 5-10 minutes of imidacloprid administration. The LD₅₀ was calculated as 131 mg/kg for males and 168 mg/kg for females. The NOAEL for systemic toxicity was 10 mg/kg, based on clinical signs in the males observed at the LOAEL of 71 mg/kg.

Meanwhile, EFSA classifies imidacloprid as a Category 4 acute oral toxicant, a category lower than that used by EPA, and notes it as “harmful if swallowed,” based on studies in rats and dogs. EFSA also describes acute oral toxicity of imidacloprid as moderate, reporting LD₅₀ values ranging from 380-650 mg/kg in rats and 131-168 mg/kg in mice. EFSA reported that most symptoms in rats and mice were reversible after 6 days.

9.3.1.2 Dermal

The EPA established its imidacloprid dermal toxicity rating (Category IV) based on a subchronic limit dose test performed by Flucke (1990, see Section 9.3.2.2). A limit dose represents a high dose test to confirm that the toxicity of the test material is below a well-recognized level when test subjects exhibit no observed response. Kroetlinger (1989) performed a similar test under acute conditions for rats and found the NOEL to be > 5000 mg/kg for 94.2% imidacloprid.

9.3.1.3 Inhalation

Imidacloprid has a low acute toxicity via the inhalation route (U.S. EPA, 2008a). This is primarily based on a study (Pauluhn, 1988a) which found technical grade imidacloprid (95.3%) to exhibit low toxicity to and no mortality in Wistar rats. This was true using both aerosol and dust forms of the chemical. The NOEL was 1220 mg/m³ and the LOEL was 2577 mg/m³ for aerosol delivery. Clinical signs at the LOEL included difficulty breathing, reduced motility and piloerection, slight tremors, and decrease of body weight gains. Since there were no mortalities, the LC₅₀ values for dust and aerosol inhalation were determined to be > 5323 mg/m³ and > 69 mg/m³, respectively. Both figures represent the highest attainable doses for this experiment (EFSA 2006). However, using an endpoint based on a rat difficulty breathing rate of 0.96 m³/kg/day can produce NOEL and LOEL values of 195 mg/kg/day and 412 mg/kg/day, respectively. The author speculates that limited bioavailability of imidacloprid due to large dust particle size may have produced an artificially high NOEL. Adjusting the dose of 195 mg/kg/day for 11% of particles with MMAD ≤ 5 µm would result in an acute inhalation NOEL of 20 mg/kg/day.

9.3.1.4 Skin irritation

Both the EPA and EFSA unequivocally state that imidacloprid is not a skin irritant. A study in rabbits by Pauluhn (1988b) of irritation/corrosive potential on the skin found that imidacloprid has no irritant effect to the skin (EFSA, 2006).

9.3.1.5 Eye irritation

Both the EPA and EFSA unequivocally state that imidacloprid is not an eye irritant. A study in rabbits by Pauluhn (1988c) of irritation/corrosive potential on the eye found that imidacloprid has no irritant effect to the eye (EFSA 2006).

9.3.1.6 Skin sensitization

Both the EPA and EFSA unequivocally state that imidacloprid is not a skin sensitizer. A study in guinea pigs by Otha (1988) of skin sensitizing potential found that imidacloprid has no such potential under the conditions of the Maximization test (EFSA 2006).

9.3.1.7 Acute Reference Dose (aRfD) and justification

EPA established the acute reference dose (aRfD) for imidacloprid at 0.14 mg/kg/day based on the decrease in motor and locomotor activities observed in female rats in an acute neurotoxicity study, with a NOAEL of 42 mg/kg/day. Recall that EPA reported this as the LOAEL, hence associated an uncertainty factor for margin of exposure of 300. This reflects factors of 10 for interspecies variation and intraspecies variation, and a factor of 3 for the use of LOAEL instead of NOAEL.

9.3.1.8 Chemical formulations

WGHOGA is seeking to use the Protector 2F (flowable) and Protector 0.5G (granular) formulations. The flowable formulation is a white, sweetly-scented liquid composed of 21.4% active ingredient (imidacloprid) and 78.6% other ingredients. The product is to be mixed with water and applied at a rate of 0.5 lb a.i./A in a single application per year.

The Protector 0.5G formulation is a brown, weakly-scented granular solid composed of 0.5% imidacloprid and 99.5% other ingredients. The product is to be applied at a rate of 0.5 lb a.i./A in a single application per year.

9.3.1.9 Exposed population

There are no populations exposed to imidacloprid contamination prior to treatment. It is illegal to use imidacloprid formulations on sediments in Willapa Bay and Grays Harbor without Washington State Department of Ecology approval and no parties have been granted such license. As discussed in Section 7.3, background imidacloprid residues were not found in these areas based on a number of field studies that recorded both pre and post application activities.

During treatment, the handlers and applicators of the chemical will face inherent exposure. Recreational swimmers will not be present at the treatment sites or in their immediate vicinities, hence will face no exposure.

Following treatment, consumers of fish, shellfish, or any commodity in contact with the treated sediment and overlying water will face some potential oral/dietary exposure. Recreational swimmers may be exposed via the dermal route and may experience inhalation exposure. Commercial workers such as fishermen, food distributors, and food handlers may experience dermal exposure and may experience some inhalation exposure.

9.3.1.10 Toxicity assessment

EPA assigns toxicity categories for various exposure routes to humans (Table 9.2). Each category is to be designated by a “signal word” that appears on the label, and the signal word also dictates what additional exposure precautions must be used when handling the material (such as the use of personal protective equipment). EPA toxicity categories are based on the levels and toxicity ranges provided by standard acute testing conducted under 40 CFR Part 158 requirements and guidelines. Table 9.2 and Table 9.3 summarize the acute toxicity categories for imidacloprid and their corresponding meanings.

Table 9.2 Acute Toxicity Categories for Imidacloprid

| Route of Exposure | Toxicity Category | |
|-------------------|-------------------|-------------------------|
| | EPA | GHS ^a (EFSA) |
| Oral | II | IV |
| Dermal | IV | - |
| Inhalation | IV | - |
| Dermal Irritation | IV | - |
| Eye Irritation | IV | - |

a = Globally Harmonized System

Source: EFSA 2006. Reprinted.

Table 9.3 EPA Acute Toxicity Categories and Signal Words

| Toxicity Category | Signal Word | |
|-------------------|-----------------|------------|
| | EPA | GHS (EFSA) |
| I | Danger | Danger |
| II | Warning | Danger |
| III | Caution | Danger |
| IV | (none required) | Warning |
| V | N/A | Warning |

Source: U.S. EPA 2012. Reprinted.

9.3.2 Pharmacokinetics – absorption, distribution, and metabolism

Pharmacokinetics is a branch of pharmacology dedicated to determining the action of drugs in the body over a period of time. This includes the processes of chemical absorption, distribution, localization in tissues, biotransformations, and excretion. The pharmacokinetic properties of a toxicant influence its toxicity, target sites, duration of exposure, and other parameters in a given species (EFSA 2006). These were studied for imidacloprid for the oral pathway; pharmacokinetic studies were not available for a direct determination of the rate of absorption from dermal and inhalation routes. The pharmacokinetic properties of imidacloprid were determined based on five studies in Wistar rats (Klein 1987, 1990a and 1990b; Klein and Karl 1990; and Klein and Brauner 1991a), two in laying hens, and two in lactating goats (Klein and Brauner 1990, 1991b; Klein, 1992 and Karl et al., 1991). The information below was based on CEPA-DPR's summary of these studies.

9.3.2.1 Oral

Imidacloprid is quickly and almost completely absorbed from the gastrointestinal tract; it is rapidly distributed in nearly all organs and tissues, and passes quickly through the body. Oral absorption was estimated to be 92-99%, based on urinary recovery after oral and intravenous dosing (CEPA-DPR, 2006). As reported by DPR, Klein observed an absorption half-life of approximately 35 minutes, taking into account a lag time of 2.5 minutes. The rate of absorption of imidacloprid via dermal and inhalation routes was not calculated. The EPA assumes 100% absorption in this case. On average, 75% of the administered radioactivity is excreted with the urine, with the remainder found in the feces. Most of the fecal radioactivity originates from biliary excretion. There is some evidence for enterohepatic circulation.

The extent of penetration of the blood-brain barrier is very limited. The metabolization rate of imidacloprid in the rat is high, and somewhat more pronounced in male than in female animals. Metabolism proceeds on two major routes, one beginning with oxidative cleavage of the methylen-bridge,

the other with the hydroxylation of the imidazolidine ring in the 4-or 5-position. The main metabolites in urine are 6-chloronicotinic acid and its glycine conjugate as well as two corresponding biotransformation products² which contain the imidazolidine ring. Further products detected in urine included two monohydroxylated metabolites³ and an unsaturated compound⁴. The latter is also excreted with the feces, together with 6-chloronicotinic acid and IMI-6-CNA-glycine.

Studies on the biokinetic and metabolic behavior of imidacloprid and its nitrosimine plant metabolite (IMI-nitrosimine) in male rats yielded comparable data for absorption, distribution, and elimination. IMI-nitrosimine was eliminated somewhat more rapidly, and the radioactivity levels in the organs were lower than after administration of imidacloprid. IMI-nitrosimine was not detected in the urine or feces following administration of single oral doses of 1 mg/kg bw or 150 mg/kg bw imidacloprid to male rats. However, after prolonged treatment (one year) at high doses of imidacloprid in the diet, IMI-nitrosimine was found in the urine of rats and mice at levels of 9 mg/100 mL (rat) and 1.5 mg/100 mL (mouse). Formation of IMI-nitrosimine from imidacloprid seems to occur when enzyme systems involved in the usual degradation reactions are saturated as it is likely to be the case after chronic feeding of high imidacloprid concentrations. The formation of IMI-nitrosimine in rats and mice has been confirmed and its toxicological properties play a role in the chronic toxicity studies with these animal species.

9.3.2.2 Dermal

The rates of absorption of imidacloprid via dermal and inhalation routes were not calculated. The EPA assumes 100% absorption in such cases.

9.3.2.3 Synergism with other pesticides

Imidacloprid has not exhibited synergistic behavior with any known compounds. The manufacturer submitted results of three acute oral studies of imidacloprid synergism to EFSA. Each study found no evidence of synergism; therefore no modifications to FIFRA toxicity ratings for imidacloprid are necessary. Consult Table 9.4 for more information from these studies.

Table 9.4 Summary of Studies of Imidacloprid Synergism with other Pesticides

| Pathway | Test Species | Imidacloprid Purity (%) | Synergism Compound | Synergism Compound Purity (%) | Conclusion | Reference |
|------------|--------------|-------------------------|--------------------|-------------------------------|--------------|-------------------|
| Acute oral | Rat | 97.6 | Cyfluthrin | 95.1% | No synergism | Kroetlinger 1994a |
| Acute oral | Rat | 97.6 | Methamidophos | 73.8 | No synergism | Kroetlinger 1994b |
| Acute oral | Rat | 98.4 | Flumethrin | 95.8 | No synergism | Andrews 2002 |

9.3.3 Subchronic toxicity

The subchronic toxicity of imidacloprid has been studied in rats, mice, rabbits, and dogs. The EPA labeled imidacloprid a Category II dermal toxicant because of its observed subchronic effects on rabbits. A subchronic study was considered to be any study of “short-term” (1-30 days) or “intermediate-term” (1-6 months) duration. Information on subchronic toxicity is consistent and there are no unusual outlying data points. Table 9.8 summarizes the studies of subchronic toxicity discussed below.

² Nitroimino imidazolidine and Nitroimino dehydroimidazolidine

³ IMI-5-hydroxy and IMI-4-hydroxy

⁴ IMI-olefine

9.3.3.1 Oral

The EPA reviewed a subchronic oral toxicity study (Sheets and Hamilton, 1994b) of imidacloprid (97.6% - 98.8%) administered to Fischer rats. There were no compound-related clinical signs or mortalities observed at any dietary level. Body weight and food consumption were reduced by treatment at doses of 963 ppm (63.3 and 69.3 mg/kg/day in males and females, respectively). The LOEL was then 963 ppm. The NOAEL for subchronic toxicity was 3027 ppm, but the overall NOEL was 140 ppm (9.3 mg/kg males; 10.5 mg/kg females).

Other short-term studies submitted by the manufacturer generally corroborate the findings detailed above. The oral studies and their corresponding results are presented below in Table 9.5.

Table 9.5 Subchronic Oral Toxicity Studies

| Type | Species | Purity | NOAEL (m/f–mg/kg) | LOAEL (m/f–mg/kg) | Reference |
|------|---------|--------|----------------------|----------------------|--------------------------|
| 90-d | Rat | 92.8 | 11/15 | 57/78 | Eiben 1988a |
| 90-d | Rat | 95.3 | 14/83 | 61/422 | Eiben 1989 |
| 90-d | Mouse | 92.8 | 391/446 | 2408/3087 | Eiben 1988b |
| 28-d | Dog | 92.8 | 7.3 | 31 | Bloch <i>et al.</i> 1997 |
| 90-d | Dog | 95.3 | 23.5 | 45.4 | Ruf and Sander 1990 |
| 12-m | Dog | 94.9 | 15 | 42/70 | Allen <i>et al.</i> 1989 |

These studies collectively found that the liver was the principal target organ, marked by elevated activities in the serum of alkaline phosphatase and alanine aminotransferase; decreased levels of protein, albumin, triglycerides and cholesterol; and the lengthening of blood clotting time. Trembling was also detected in all dogs treated with at least 600 ppm imidacloprid. Rats and dogs experienced reduced food intake and weight reduction.

9.3.3.2 Dermal

The EPA reports that imidacloprid has a low subchronic toxicity via the dermal route and is thus designated a Category IV dermal toxicant (U.S. EPA, 2008a). This is primarily based on a limit dose study (Flucke, 1990) in New Zealand rabbits. Imidacloprid (95.0%) was tested in 5 male/5 female rabbits at 1000 mg/kg. There were no mortalities and no significantly different behaviors between treatment and control groups were observed. The NOEL for this study was then >1000 mg/kg.

9.3.3.3 Inhalation

The EPA reports that imidacloprid has a low subchronic toxicity via the inhalation route and is thus designated a Category IV inhalation toxicant (U.S. EPA, 2008a). This is primarily based on a 28-d inhalation study (Pauluhn, 1988a) in which rats were exposed to 95.3% imidacloprid for five consecutive days. All rats tolerated the treatment without symptoms and no mortalities occurred. A slight, transient effect on the body weight development was observed at exposure of 109 mg/m³ air onwards. An induction of mixed-function oxidases occurred as well. The NOAEC was reported to be 20 mg/m³.

Another study by Pauluhn (1989) observed elevated mixed-function oxidase activities in the liver homogenate of females at 30.5 mg/m³ air and above, and in males at 191.2 mg/m³ air. Other symptoms included adverse effects on the liver at these levels and above. The NOAEC for this test was reported to be 5.5 mg/m³ air, equivalent to 2.4 mg/kg/day.

9.3.3.4 Neurotoxicity

EFSA cites a subchronic oral neurotoxicity study in Fischer 344 rats by Sheets and Hamilton (1994b), which found that imidacloprid caused no mortalities or compound-related clinical signs at any dietary level. Body weight and food consumption were reduced by treatment at doses of 9.3 and 10.5 mg/kg/day for males/females, respectively. The NOAEL for subchronic neurotoxicity was found to be 196 and 213 mg/kg/day for males/females, respectively (or 3.027 ppm).

9.3.3.5 Immunotoxicity

Studies specifically evaluating immunotoxicity effects resulting from imidacloprid were not available. EPA has listed such a study among its data requirements for imidacloprid in Registration Review materials, but, due to the uncertainty with respect to the actual value of conducting such a study, it is common for data generated in other toxicity studies to be used to address this endpoint. There is no evidence from other studies that imidacloprid has adverse effects on the immune system.

9.3.3.6 Estrogen disruption

Bayer CropSciences, the leading manufacturer of imidacloprid, submitted the results of 11 bioassays to the EPA for the purpose of completing the Endocrine Disruptor Screening Program (EDSP) Tier 1 screening requirement for imidacloprid. Bayer claimed that the tests were functionally equivalent to the EDSP Tier 1 screening battery because the data produced were of a suitable nature and quality to provide the same essential predictive information, even if different methods and procedures were used. Based on these tests, Bayer concluded that there was no indication for estrogenic, anti-estrogenic, anti-androgenic or thyroid properties (Sheets and Fischer 2010).

The Endocrine Disruptor Review Team (EDRT) reviewed the bioassays and denied the manufacturer's submission to pass the Tier 1 screening battery, citing deficiencies such as information gaps and false assumptions (Akerman 2010). Part of this debate is related to the nature of tests that ultimately will be routinely required by EPA to evaluate estrogen disruption. A testing battery has been developed based on validated but new study protocols, and early results suggest that the test results are inconsistent, giving little or no more information than do EPA's current pesticide study requirements.

Despite EDRT's review, there is no indication that imidacloprid is prone to cause estrogen disruption—particularly in humans. The comments received from EDRT by the manufacturer suggest further and more specific testing is required, but do not question the manufacturer's scientific results or general conclusion that imidacloprid is unlikely to produce adverse estrogenic disruption effects in humans.

9.3.3.7 Subchronic reference doses and justification

The EPA has established the subchronic reference dose for imidacloprid at 0.100 for all short-term exposure routes and 0.093 for all intermediate-term exposure routes. These reference doses are based on NOAEL = 10 mg/kg/day and 9.3 mg/kg/day for short-term and intermediate-term exposures, respectively. This reflects factors of 10 for intraspecies variation and interspecies variation.

9.3.4 Chronic toxicity

The studies identified by EPA as influential in its chronic toxicity ratings for the oral route are discussed below. The results of related and/or corroborating studies are also presented.

9.3.4.1 Oral

The EPA reviewed a chronic oral toxicity study (Allen *et al.* 1989) of imidacloprid (94.9%) administered to dogs. There were no signs of altered appearance, behavior, body weight gain, trembling, or mortalities observed at the highest dose. Initial slight reductions in food intake were observed in both sexes at 1250 and 2500 ppm. The NOAEL was 500 ppm, equivalent to 15 mg/kg/day. The LOAEL was 1250/2500 ppm, based on slightly elevated liver weight, plasma cholesterol, and cytochrome P-450.

Other chronic oral studies by Eiben and Kaliner (1991) and Watta-Gebert (1991) generally corroborate the findings detailed above. The NOAEL reviewed by EPA falls between the NOAELs for these two studies. Consult Table 9.6 for details of the chronic studies used by EPA.

Table 9.6 Chronic Toxicity Studies

| Type | Species | Purity | NOAEL (m/f-mg/kg) | LOAEL (m/f-mg/kg) | Reference |
|------|---------|------------|----------------------|----------------------|-------------------------|
| 24-m | Rat | 94.3-95.3% | 6/25 | 17/73 | Eiben and Kaliner, 1991 |
| 24-m | Mouse | 95.3% | 66/104 | 208/274 | Watta-Gebert, 1991 |

These studies found that rats and mice undergo significant weight loss from chronic oral exposure to imidacloprid. Rats were observed to have lesions in the thyroid gland and experienced a dose-dependent increase in the incidence and severity of mineralized particles in the thyroid follicles. This occurrence is generally considered a sign of biological aging. Various types of tumors were also reported in rats but there was no difference in incidence and type from that found in the controls. In contrast, the main effects on mice were peri-acinar hypertrophy of hepatocytes in males and mineralization of thalamus in females.

9.3.4.2 Chronic Reference Dose (cRfD) and justification

There appears to be a discrepancy between reported values of cRfD in EPA's federal register notice and EPA-EFED's Human Health Scoping Document for imidacloprid. This stems from a difference in uncertainty factors (UFs). Both documents report a NOEL of 5.7 mg/kg/day and a LOEL of 16.9/24.9 mg/kg/day for males/females respectively; however, the federal register uses an UF of 300 while the scoping document uses an UF of 100 (U.S. EPA 2008a). The difference between these UFs—a factor of 3—is typically assigned when calculating a reference dose from the LOEL when the NOEL is unavailable. Because this is not the case (NOEL = 5.7 mg/kg/day), it is appropriate to use an UF of 100. Thus the cRfD reported in the human scoping document is presented here as 0.057 mg/kg/day.

9.3.5 Reproductive and developmental toxicity

EPA found no evidence of increased qualitative or quantitative susceptibility of rats or rabbits to *in utero* exposure to imidacloprid and no evidence of qualitative or quantitative susceptibility of offspring, based on rat and rabbit studies by Becker *et al.* (1988a,b) and Suter *et al.* (1990). There was evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study. At the highest dose tested, maternal effects consisted primarily of slight decreases in food consumption and body-weight gain during early lactation. Pup effects included decreased body weight, motor activity, and caudate/putamen width in females. Slight changes in performance in the water maze were observed in males at the same dose. Imidacloprid is not considered to induce reproductive toxicity or teratogenicity since there were no effects in offspring in absence of direct toxic effects in the dams.

9.3.6 Carcinogenicity and mutagenicity

The EPA used the chronic toxicity studies by Eiben and Kalimer (1991) and Watta-Gebert (1991) discussed above in its determination of carcinogenicity. The EPA found no evidence of carcinogenicity or

carcinogenic potential resulting from imidacloprid. The Reference Dose/Peer Review Committee has designated imidacloprid a Group E chemical, which means there exists no evidence of carcinogenicity for humans, by all routes of exposure, based upon lack of evidence of carcinogenicity in rats and mice.

A final rule for imidacloprid's pesticide tolerance published in the Federal Register explicitly states that mutagenicity studies have demonstrated imidacloprid to be non-mutagenic both *in vivo* and *in vitro* (#40 CFR Part 180, 1998). An earlier Federal Register notice (#40 CFR Part 180, 1995) stated imidacloprid to show weak mutagenic effects in 2 of 23 mutagenic bioassays. Specifically, imidacloprid tested positive for chromosome aberrations in an *in vitro* cytogenetic study with human lymphocytes for the detection of induced clastogenic effects (Herbold 1989), and for genotoxicity in an *in vitro* cytogenetic assay measuring sister chromatid exchange in Chinese hamster ovary cells (Taalman 1988). An explanation of EPA's change in ruling was not found.

9.3.7 Epidemiology

A summary report listing incidents for imidacloprid reported to the OPP Incident Data System (IDS) was published in 2008 (U.S. EPA 2008c). The report cites incidents occurring in the U.S. from 2000 to 2008 for imidacloprid only. Approximately 400 incidents were reported during this period. There appears to be no demographic trend in the complaints. Each incident is characterized by direct exposure to unusually high concentrations of imidacloprid and likely resulted from misuse or mishandling of the formulated product.

The 2011 EFSA report mentioned mild cases of contact dermatitis in pet owners following use of veterinary formulations of imidacloprid. These effects were attributed to formulation-specific components of the product but not to imidacloprid itself.

9.3.8 Human case reports and studies

Appendix E comprises the aforementioned incident reports published by EPA in 2008.

9.4 Exposure assessment

9.4.1 Potential routes of exposure

The EPA-HED and EFSA human health documents both assessed the following major exposure routes of imidacloprid: residential, dietary, short-term aggregate (residential + dietary) and applicator/occupational. These are addressed below and related to how or whether the use such as that proposed for oysters would be expected to exceed the exposure scenarios EPA has already examined.

In Willapa Bay and Grays Harbor, there will be potential for dermal exposure from recreational swimming/wading, in addition to the exposure scenarios EPA has examined. There will also be potential for increased dietary exposure, particularly for populations such as local Native American tribes that consume a relatively high proportion of fish and shellfish. In contrast, significant residential exposure is not expected because the proposed use for imidacloprid is purely commercial and to be applied in a commercial setting.

9.4.1.1 Residential exposure

Imidacloprid is currently registered for use on the following residential sites: ornamentals, tobacco, golf courses, walkways, recreational areas, bathrooms, household or domestic dwellings (indoor/outdoor), cats/dogs, and wood protection treatment to buildings. In comparison to these uses, any potential residential exposure from imidacloprid use on oyster beds is an extremely low contribution to total exposures already evaluated by regulatory agencies.

The EPA-HED examined imidacloprid exposure scenarios for residential handlers and post-application dosing. Seven residential handler scenarios were assessed and their MOEs for dermal and inhalation routes calculated using application rate, daily amount applied, unit exposure, and dose (Table 9.7). EPA evaluated both residential handlers and residential post-application exposures and reached the conclusion that there is sufficient information available to assess residential exposure. Treated lawns and treated pets present the highest exposure scenarios. EPA did not assess the wood preservative and termiticide use scenarios because the turf and pet use scenarios, passing the risk screen with much lower margins of exposure even for toddlers, made any risk contribution from these uses negligible.

It was established in Section 9.4.1 that residential exposure is not expected to influence the risk assessment for use of imidacloprid in Willapa Bay or Grays Harbor. HED human health documents do not mention exposure routes following commercial treatments such as that proposed for shellfish. However, potential incidental exposure of residences presents such a low exposure level that it can be assumed to be much less than that posed, for example, by termiticide or wood treatment uses where risk was determined to be negligible. Any casual exposure to bystanders or individuals entering areas where treatments on shellfish beds have taken place would be one-time and of short duration to low concentrations, and present a much lower profile of exposure than does exposure from residential or pet product use.

Table 9.7 Summary of Short-term Residential Handler Exposure and Risks

| Scenarios Assessed | DP# | Application Rate | Area Treated/Amount Applied (per day) | Unit Exposure (per lb ai handled) | | Dose (mg/kg/day) | | MOE | |
|---|--------|------------------------------------|---|-----------------------------------|---------|------------------|-----------|------------|--------|
| | | | | Inhalation | Dermal | Inhalation | Dermal | Inhalation | Dermal |
| Granular/push-type spreader application | 281610 | 0.4 lb ai/A | 0.5 A | 0.00091 lb | 0.68 lb | 0.0000026 | 0.000136 | 72,150 | |
| Ready-to-use trigger pump spray | | Negligible, see horse-end spray | | | | | | | |
| Potted plant spikes | | 10 two gram spikes or 0.0011 lb ai | 10 plants | Negligible | 356 mg | Negligible | 0.00392 | Negligible | 2600 |
| Plant potting medium | | 0.00288 | 1 container | Negligible | 3560 mg | Negligible | 0.01 | Negligible | 1000 |
| Garden hose-end spray | | 0.0002196 lb ai/1000 ft² | 22,000 ft² | 11.0 mg | 0.016 | 11.0 mg | 0.0000011 | 185,000 | |
| Soil drench bucket/water can | | 0.245 lb ai/day | 20 medium trees or 42 average-size shrubs | 0.0012 | 2.9 mg | 0.0012 | 0.0007 | 14,000 | |
| Pet spot on | | 4.9 mg/ai day | 1 dog | Negligible | 48.8 mg | Negligible | 0.025 | Negligible | 400 |

Source: U.S. EPA 2008. Human health assessment scoping document. Reprinted.

9.4.1.2 Dietary exposure

Because imidacloprid is registered for use on many crops, EPA and Europe have established tolerances for residues in the edible portions of plants and animals. In the United States, there are over 100 tolerances set for imidacloprid, covering most edible foods and a range of concentrations. The tolerances for meat items such as pork and beef are 0.30 ppm and the tolerance in poultry meat is 0.05 ppm (40 CFR 180.472). The tolerance proposed and accepted for the use in oysters is also 0.05 ppm. The only commodity with a tolerance set lower than 0.05 ppm is the tolerance for eggs, which is 0.02 ppm. Most tolerances are set at higher levels, generally between 0.5 and 3.0 ppm but also ranging significantly higher in certain food items.

The EPA-HED conducted an unrefined acute and partially refined chronic dietary exposure assessment in May 2007 that considered all tolerances established at that time. The existence of an unrefined exposure assessment means that a more refined assessment was not needed in order for the labeled uses to pass the risk criteria screen. The assessment used the Dietary Exposure Evaluation Model (DEEM-FCIDTM, Version 2.03) which uses food consumption data from the USDA. Because there is no tolerance set for imidacloprid residues in drinking water, concentrations potentially present in water were estimated through standard modeling procedures. The acute assessment incorporated drinking water exposure using the peak concentration for surface water generated by the FQPA Index Reservoir Screening Tool (FIRST) model to produce estimates in relation to the acute population adjusted dose (aPAD). The chronic assessment also used the FIRST model, to produce chronic exposure estimates for the U.S. population and various population subgroups in relation to the chronic population adjusted dose (cPAD).

9.4.1.3 Short-term aggregate exposure

Four short-term aggregate (dietary, residential, and post-application) exposure scenarios were considered for EPA's assessment because there is potential for individuals to be exposed concurrently through these routes (see Table 9.8). High-end estimates of the residential exposure and average dietary exposures were used. The pet-treatment residential scenario resulted in the lowest combined MOE for adults and children; therefore, the pet-treatment exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1-2 years old (the child population subgroup with the highest estimated chronic dietary food exposure).

The short-term aggregate exposure assessment described above is not expected to be influenced by the risk of proposed imidacloprid use at Willapa Bay and Grays Harbor because the residential handler and post-application exposure routes are largely inapplicable. While there is some concern for an aggregate exposure scenario involving recreational swimmers (dermal), bystanders and fish/shellfish consumers (dietary), this concern can be addressed under the current risk scenarios.

Table 9.8 Exposure Potential for Adult and Child Short-term Aggregate Risk Estimates

| Exposure Scenario | | Exposure (Dose) mg ai/kg bw/day | MOE | Combined Exposure (Dose) mg ai/kg bw/day | Combined MOE ⁵ |
|------------------------|---|---------------------------------|------------------|--|---------------------------|
| Toddler – Treated Turf | Oral hand-to-mouth post-application exposure from contacting treated turf | 0.0059 | 1,700 | 0.00692 | 1,500 |
| | Incidental oral post-application exposure from ingestion of treated soil | 0.00002 | 500,000 | | |
| | Dermal post-application exposure from contacting turf | 0.001 | 10,000 | | |
| Toddler – Treated Pet | Incidental oral post-application exposure from contacting treated pet | 0.00276 | 3,600 | 0.03876 | 260 |
| | Dermal post-application exposure from pet “hug” / contacting treated pet | 0.036 | 280 | | |
| Adult – Treated Turf | Handler dermal and inhalation exposure from applying imidacloprid using granular/push-type spreader | 0.0000139 | 72,000 | 0.000669 | 15,000 |
| | Dermal post-application exposure from contacting treated turf | 0.00053 | 19,000 | | |
| Adult – Treated Pet | Handler dermal and inhalation exposure from applying imidacloprid to pet with pet spot-on | 0.025 | 400 ⁶ | | |
| | Dermal post-application exposure from contacting treated pet | | | | |

Source: U.S. EPA 2008. Human health assessment scoping document. Reprinted.

9.4.1.4 Applicator/Occupational Exposure

The EPA-HED relied on surrogate unit exposures from the Pesticide Handler Exposure Database (PHED) to assess potential exposure to pesticide handlers, and a proprietary study (not cited) to assess exposure to commercial seed handlers. Handlers’ exposure and risk were calculated at two levels of mitigation: “baseline” (long pants, a long-sleeved shirt, no chemical-resistant gloves,

⁵ Combined MOEs are presented for toddler oral + dermal exposure to treated turf, and oral + dermal exposure to a treated pet. Combined MOEs are expressed as: MOE DERMAL + MOE ORAL. Combined MOEs are presented for an adult who applies the material to his/her lawn and then experiences post-application exposure.

⁶ HED believes handler exposure will be negligible. However, the results from an unpublished study (see residential post-application exposure to treated pets) were used to measure possible post-application exposure.

and no respirator) and “personal protective equipment” (baseline clothing with chemical-resistant gloves when necessary).

None of these scenarios describe the treatment of flowable and/or solid granule formulations on commercial shellfish beds or other sediment. However, the formulations registered for this use are already registered for other uses and the application methods and concentrations employed in those registered uses are equivalent to the methods on the new labels for use in oyster beds. The label instructions associated with both formulations proposed for imidacloprid treatment in Willapa Bay and Grays Harbor mandate stringent safety measures beyond the more stringent of EPA’s levels of mitigation. Applicators are to wear baseline clothing, chemical-resistant gloves made of waterproof material, shoes and socks, protective eyewear when working in non-ventilated spaces, and a dusk mask (granular formulation only). Hence, EPA’s calculated levels of risk should be considered conservative for this assessment.

9.4.1.5 Incidental exposure from recreation

There is potential for incidental dermal and ocular exposure to individuals swimming or wading in waters overlying or near areas of treated sediment. The EPA did not examine this or any similar scenarios. However, EPA did assess at least two exposures that can be compared to incidental exposures like this: pet and turf uses. EPA has also considered incidental exposure from other registered recreational uses in their risk assessment process.

9.4.2 Exposure route summary

The likeliest route of exposure for a large segment of the population is through dietary intake of contaminated commercial shellfish. Exposure to imidacloprid is increased in scenarios that include dietary intake and recreational swimming/wading, which EPA did not consider individually because such exposure was deemed negligible in light of exposures presented by other registered uses.

10. Risk Assessment and Characterization for Health Effects

10.1 Residential exposure results and characterization

The proposed treatment of sediment beds in Willapa Bay/Grays Harbor is strictly commercial; hence there are no direct residential exposures expected. There is no reasonable risk of handlers using the proposed formulations on residential property, or of commercial treatments contaminating residential property under the labeling accepted for oyster beds. Imidacloprid is approved for use in many residential settings. Any added residential risk associated with proposed oyster bed usage under approved label instructions is considered negligible. This consideration is supported by the negligible contribution of residential exposures expected for other types of use scenarios where direct residential handling and application is not anticipated.

10.2 Dietary exposure results and characterization

EPA conducted an unrefined acute dietary exposure assessment for the general U.S. population and various population subgroups (U.S. EPA-OPPTS, 2008). The assessment found that acute dietary exposure estimates were below HED’s level of concern, <100% of the aPAD at the 95th exposure percentile for the general population and all subgroups. The most highly exposed population subgroup was children 1-2 years old, at 70% of the aPAD. It is expected that children are among the least likely subgroups to consume high levels of shellfish.

EPA also conducted a partially-refined chronic dietary exposure assessment for the U.S. population and various population subgroups (U.S. EPA-OPPTS, 2008). The assessment found that that chronic dietary exposure estimates were below HED's level of concern (100% of the cPAD) for the general population (13% of cPAD) and all population subgroups. The most highly exposed subgroup was children 1-2 years old, at 38% of cPAD⁷. It is important to note that the DEEM model used here assumes exposure from drinking water consumption. While marine and estuarine waters are not drinking water sources, when drinking water and the existing tolerances for imidacloprid are considered, the additional dietary contribution from oysters and clams from treated Willapa Bay or Grays Harbor areas is negligible.

To ensure the above assumption is supportable, the conservative scenario of a 1-2 year old infant consuming an adult-portion serving size of uncooked shellfish daily is here considered. The EPA is expected to set a shellfish tolerance at the level of detection based on residue study results—0.05 mg/kg/day. Applying this tolerance to the serving size of an uncooked entrée of shellfish used in DEEM analysis—110 g—yields an intake of .0055 mg imidacloprid daily. Assuming the average weight of a 2 year-old infant—13.5 kg (Ogden et al., 2004)—produces an exposure of 0.00041 mg/kg/day. Since 38% of the cPAD is occupied, there remains a maximum of 62% of 0.057 mg/kg/day, or 0.03534 mg/kg/day of “other” allowed exposure. Therefore, an infant could consume 86 serving sizes of shellfish every day before surpassing the established cPAD.

There exists potential for chronic exposure to be higher than 0.00041 mg/kg/day if, in addition to the conservative assumptions outlined above, intake of imidacloprid-exposed fish or other recreational catch occurs near or in treated waters. Potentially elevated exposure to local Native American tribes should also be assumed, since coastal tribal cultures consume levels of fish and shellfish at a higher rate than does the general population. Fish are typically consumed in significantly higher amounts than shellfish based on frequency (not serving size). However, imidacloprid concentrations in fish are expected to be lower because (1) the water overlying treated sediments will greatly dilute the initial concentration, and (2) fish fat content is lower, hence fish would not retain imidacloprid as easily on a per weight basis. Also, in theory, the assumed daily intake of shellfish could be doubled or even quadrupled to produce higher exposure estimates. However, none of these extreme adjustments are significant enough to affect the overall risk assessment because the cPAD cannot reasonably be reached. Additionally, consumption rates for meats with imidacloprid tolerances, such as beef, pork, and poultry, are much higher on an annual basis than would be incidental exposure to fish caught in the area of oyster bed treatments.

10.3 Applicator exposure results and characterization

EPA-HED did not assess the exact scenarios detailed in Section 9.4.1.4. However, twenty representative scenarios for commercial occupational handlers were studied, all of which were found to have acceptably low exposure risk (MOE > 100). HED further noted that similar scenarios are not of concern, provided handlers use label-prescribed personal protective equipment. The majority of these scenarios assumed an application rate of 0.5 lb a.i./A per day, while the proposed rate in Willapa Bay and Grays Harbor is 0.5 lb a.i./A per year.

Since imidacloprid has a low vapor pressure and its intended use is on outdoor sediment beds, the risk of post-application inhalation is minimal. EPA has not conducted a dermal post-application risk assessment, so the restricted-entry interval (REI) is based on the acute toxicity of imidacloprid. Imidacloprid is deemed a Category IV acute dermal toxicant. The Worker

⁷ The cPAD is assumed to equal the cRfD (0.057 mg/kg/day) for this analysis.

Protection Standard (WPS) for Agricultural Pesticides has established a default REI of 12 hours for active ingredients classified as acute toxicity categories III or IV for oral or dermal entry, which HED has adopted for imidacloprid use. The WPS allows workers to enter treated areas without restriction, provided there will be no contact with anything that has been treated with the pesticide.

10.4 Incidental exposure from recreation results and characterization

The NOEL for imidacloprid from dermal exposure was found to be > 5,000 mg/kg/day for 94.2% imidacloprid. Assuming the weight of an average 5 year-old child (20.9 kg; Ogden et al., 2004), a minimum 104.5 g dose of imidacloprid is required to approach the limit test no effect dose. The epidermis is a relatively effective barrier against water, so only a minimal uptake of salt water from Willapa Bay or Grays Harbor would be expected. There is no reasonable scenario involving incidental exposure from swimming and/or wading that would result in individuals receiving imidacloprid doses in excess of 5,000 mg/kg/day. It is also noted that a high level of dilution from the water body would be expected to reduce the initial imidacloprid concentrations before the toxicant were to reach the epidermis.

10.5 Chronic exposure

There was a need to apply quantitative measures to determine the chronic exposure levels resulting from dietary intake of imidacloprid (see Section 10.2). The analysis showed that exposure exists at levels too low to elicit concern, even in highly conservative scenarios. Use of imidacloprid in oyster beds is not continuous so chronic recreational exposure from this use would not be expected. There is no concern for chronic exposure in residential or applicator contexts. Even in scenarios for other registered uses which take place with frequency and at higher rates, chronic exposure to imidacloprid in humans was not expected to result in any adverse effects.

10.6 Uncertainties

Because imidacloprid is generally considered non-toxic to humans, the principal source of uncertainty lies with the applicator's ability to follow label instructions. There has been sufficient research on rats, mice, rabbits, and dogs to determine and accept the risk of toxicity in humans. Furthermore, numerous incident reports indicate that while overexposure can produce undesirable effects such as eye irritation, dermal irritation, and hives, imidacloprid is nonlethal to humans. This, in concert with the low risk of exposure for commercial handlers and residents, lowers uncertainty. The conservative assumptions in EPA's risk assessments confirm these determinations. However, failure to adhere to label instructions for any chemical, including imidacloprid, would introduce some uncertainty.

10.7 Conclusions

Under current labels, effects on human health as a result of residential, dietary, or occupational exposure appear to be low as a result of the low application rates relative to the toxicity of imidacloprid and to the rates and exposures generated from other registered uses. There is sufficient data on the chemistry, fate, toxicity, and exposure to conclude that adverse effects to human health due to imidacloprid are not expected if label directives are followed.

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APPENDIX A. Mallet 2F Material Safety Data Sheet

APPENDIX

MATERIAL SAFETY DATA SHEET

MALLET® 2 F T & O INSECTICIDE

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Mallet® 2 F T&O Insecticide
EPA Reg. No.: 228-695
Synonyms: Imidacloprid; 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine
Product Type: Insecticide

Company Name: Nufarm Americas Inc.
 150 Harvester Drive, Suite 200
 Burr Ridge, IL 60527

Telephone Numbers: For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident,
 Call CHEMTREC Day or Night: 1-800-424-9300
 For Medical Emergencies Only, Call 1-877-325-1840

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Sections Revised: New

2. HAZARDS IDENTIFICATION

Emergency Overview:

Appearance and Odor: Off-white colored liquid.

Warning Statements: Caution. Keep out of reach of children. Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing.

Potential Health Effects:

Likely Routes of Exposure: Inhalation, eye and skin contact.

Eye Contact: Minimally irritating based on toxicity studies.

Skin Contact: Mildly toxic and non-irritating based on toxicity studies.

Ingestion: Slightly toxic if ingested based on toxicity studies.

Inhalation: Low inhalation toxicity based on toxicity studies.

Medical Conditions Aggravated by Exposure: Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis. Skin contact may aggravate existing skin disease.

See Section 11: TOXICOLOGICAL INFORMATION for more information.

Potential Environmental Effects:

This product is toxic to wildlife and highly toxic to aquatic invertebrates. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds.

See Section 12: ECOLOGICAL INFORMATION for more information.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| COMPONENT | CAS NO. | % BY WEIGHT |
|---|-------------|-------------|
| Imidacloprid | 138261-41-3 | 21.4 |
| Inert Ingredients Including Propylene Glycol | 57-55-6 | 78.6 |

January 14, 2010

Page 1 of 6



4. FIRST AID MEASURES

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note to Physician: No specific antidote is available. Treat the patient symptomatically.

5. FIRE FIGHTING MEASURES

Flash Point: Not applicable due to aqueous formulation

Autoignition Temperature: Not determined

Flammability Limits: Not determined

Extinguishing Media: Recommended for large fires: foam or water spray. Recommended for small fires: dry chemical or carbon dioxide.

Special Fire Fighting Procedures: Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full fire-fighting turn out gear. Dike area to prevent runoff and contamination of water sources. Dispose of fire control water later.

Unusual Fire and Explosion Hazards: If water is used to fight fire, contain runoff, using dikes to prevent contamination of water supplies. Dispose of fire control water later.

Hazardous Decomposition Materials (Under Fire Conditions): May produce gases such as hydrogen chloride, hydrogen cyanide, and oxides of carbon and nitrogen.

National Fire Protection Association (NFPA) Hazard Rating:

Rating for this product: Health: 1 Flammability: 1 Reactivity: 0

Hazards Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate protective gear for the situation. See Personal Protection information in Section 8.

Environmental Precautions: Prevent material from entering public sewer systems or any waterways. Do not flush to drain. Large spills to soil or similar surfaces may necessitate removal of topsoil. The affected area should be removed and placed in an appropriate container for disposal.

Methods for Containment: Dike spill using absorbent or impervious materials such as earth, sand or clay. Collect and contain contaminated absorbent and dike material for disposal.

Methods for Cleanup and Disposal: Pump any free liquid into an appropriate closed container. Collect washings for disposal. Decontaminate tools and equipment following cleanup. See Section 13: DISPOSAL CONSIDERATIONS for more information.

Other Information: Large spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies.

7. HANDLING AND STORAGE

Handling:

Avoid contact with skin, eyes or clothing. Keep children and pets away from treated area until dry. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove

MATERIAL SAFETY DATA SHEET**MALLET® 2 F T & O INSECTICIDE**

clothing/Personal Protective Equipment (PPE) immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Storage:

Store in cool, dry place and in such a manner as to prevent cross-contamination with other pesticides, fertilizers, food and feed. Store in original container and out of the reach of children, preferably in a locked storage area. Do not contaminate water, food, or feed by storage or disposal.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Engineering Controls:**

Where engineering controls are indicated by specific use conditions or a potential for excessive exposure, use local exhaust ventilation at the point of generation.

Personal Protective Equipment:

Eye/Face Protection: Not normally required, except when working in a non-ventilated space. To avoid contact with eyes, wear chemical goggles or shielded safety glasses. An emergency eyewash or water supply should be readily accessible to the work area.

Skin Protection: To avoid contact with skin wear long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves made of any waterproof material. An emergency shower or water supply should be readily accessible to the work area.

Respiratory Protection: Not normally required. If vapors or mists exceed acceptable levels, wear NIOSH approved air-purifying respirator with cartridges/canisters approved for use against pesticides.

General Hygiene Considerations: Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material: 1) do not store, use and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored; 2) wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics or using the toilet.

Exposure Guidelines:

| Component | OSHA | | ACGIH | | Unit |
|------------------|-----------|------|-------|------|-------------------|
| | TWA | STEL | TWA | STEL | |
| Imidacloprid | NE | NE | NE | NE | NE |
| Propylene Glycol | 10 (WEEL) | NE | NE | NE | mg/m ³ |

NE = Not Established

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Off-white colored liquid.

Boiling Point: Not determined

Density: 9.2 pounds/gallon

Evaporation Rate: Not determined

Freezing Point: Not determined

pH: 7 - 8

Solubility in Water: Dispersible

Specific Gravity: 1.111 @ 20°C

Vapor Density: Not determined

Vapor Pressure: Not determined

Viscosity: 103.1 mPas @ 20°C

Note: Physical data are typical values, but may vary from sample to sample. A typical value should not be construed as a guaranteed analysis or as a specification.

10. STABILITY AND REACTIVITY

Chemical Stability: This material is stable under normal handling and storage conditions.

Conditions to Avoid: Excessive heat. For imidacloprid, strong exothermal reaction above 200°C.

Incompatible Materials: Not known

Hazardous Decomposition Products: Under fire conditions may produce gases such as hydrogen chloride, hydrogen cyanide, and oxides of carbon and nitrogen.

Hazardous Reactions: Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION**Toxicological Data:**

Data from laboratory studies conducted on a similar, but not identical, formulation:

Oral: Rat LD₅₀: >4,000 mg/kg

Dermal: Rabbit LD₅₀: >2,000 mg/kg

Inhalation: Rat 4-hr LC₅₀: >5.33 mg/L

Eye Irritation: Rabbit: Minimally irritating

Skin Irritation: Rabbit: Non-irritating

Skin Sensitization: Not a contact sensitizer in guinea pigs following repeated skin exposure.

Subchronic (Target Organ) Effects: Repeated overexposure to imidacloprid, may affect heart, thyroid, blood chemistry, and liver. Overexposure to propylene glycol has been associated with kidney toxicity, liver toxicity (animals) and lactic acidosis. Very high dose acute exposure may result in CNS and cardiac effects.

Carcinogenicity / Chronic Health Effects: Prolonged overexposure to imidacloprid can cause effects to the thyroid. Imidacloprid did not cause cancer in laboratory animal studies. The U.S. EPA has given imidacloprid a Group E classification (evidence of non-carcinogenicity in humans). Overexposure to propylene glycol has been associated with kidney toxicity, liver toxicity (animals) and lactic acidosis.

Reproductive Toxicity: In a two-generation reproduction study in rats, imidacloprid produced reduced mean body weights and body weight gains. No other reproductive effects were observed. In the mouse, propylene glycol was not a reproductive toxicant.

Developmental Toxicity: Rat and rabbit studies on imidacloprid resulted in skeletal abnormalities, increased resorptions (rabbits) and reduced body weight gains at doses that were also toxic to mother animals. In a series of animal studies, propylene glycol was not a developmental toxicant.

Genotoxicity: The imidacloprid mutagenicity studies, taken collectively, demonstrate that imidacloprid is not genotoxic or mutagenic. Propylene glycol was consistently nonmutagenic.

Assessment Carcinogenicity: None listed with ACGIH, IARC, NTP or OSHA.

See Section 2: HAZARDS IDENTIFICATION for more information.

12. ECOLOGICAL INFORMATION**Ecotoxicity:**

Data on Imidacloprid Technical:

| | | | |
|---|---------------|--|--------------|
| 96-hour LC ₅₀ Rainbow Trout: | 211 mg/l | Japanese Quail Oral LD ₅₀ : | 31 mg/kg |
| 48-hour EC ₅₀ Daphnia: | 85 mg/l | Bobwhite Quail Oral LD ₅₀ : | 152 mg/kg |
| 96-hour LC ₅₀ Mysid: | 0.038 ppm | House Sparrow Oral LD ₅₀ : | 41 mg/kg |
| 48-hour Honey Bee Oral LD ₅₀ : | 0.0039 µg/bee | 48-hour Honey Bee Contact LD ₅₀ : | 0.078 µg/bee |

Environmental Fate:

Hydrolysis half-life of imidacloprid is greater than 30 days at pH 7 and 25°C. The aqueous photolysis half-life is less than 3 hours. The soil surface photolysis of imidacloprid has a half-life of 39 days, and in soil, the half-life ranged from 26 to 229 days.

13. DISPOSAL CONSIDERATIONS**Waste Disposal Method:**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling and Disposal:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke.

14. TRANSPORTATION INFORMATION

Follow the precautions indicated in Section 7: HANDLING AND STORAGE of this MSDS.

DOT

Non Regulated

IMDG

UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S., (IMIDACLOPRID), 9, III, MARINE POLLUTANT

IATA

Non Regulated

15. REGULATORY INFORMATION**U.S. Federal Regulations:**

TSCA Inventory: This product is exempted from TSCA because it is solely for FIFRA regulated use.

SARA Hazard Notification/Reporting:

Hazard Categories Under Criteria of SARA Title III Rules (40 CFR Part 370):

Immediate

Section 313 Toxic Chemical(s):

None

Reportable Quantity (RQ) under U.S. CERCLA:

None

RCRA Waste Code:

None

State Information:

Other state regulations may apply. Check individual state requirements.

California Proposition 65: Not Listed

| |
|-----------------------|
| 16. OTHER INFORMATION |
|-----------------------|

This Material Safety Data Sheet (MSDS) serves different purposes than and DOES NOT REPLACE OR MODIFY THE EPA-ACCEPTED PRODUCT LABELING (attached to and accompanying the product container). This MSDS provides important health, safety and environmental information for employers, employees, emergency responders and others handling large quantities of the product in activities generally other than product use, while the labeling provides that information specifically for product use in the ordinary course.

Use, storage and disposal of pesticide products are regulated by the EPA under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through the product labeling, and all necessary and appropriate precautionary, use, storage, and disposal information is set forth on that labeling. It is a violation of Federal law to use a pesticide product in any manner not prescribed on the EPA-accepted label.

Although the information and recommendations set forth herein (hereinafter "Information") are presented in good faith and believed to be correct as of the date hereof, Nufarm Americas Inc. makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Nufarm Americas Inc. be responsible for damages of any nature whatsoever resulting from the use of or reliance upon Information. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS.

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APPENDIX B. Mallet 0.5G Material Safety Data Sheet

APPENDIX

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Mallet® 0.5G Insecticide
EPA Reg. No.: 228-501
Synonyms: Imidacloprid; 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine
Product Type: Insecticide

Company Name: Nufarm Americas Inc.
150 Harvester Drive, Suite 200
Burr Ridge, IL 60527

Telephone Numbers: For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident,
Call CHEMTREC Day or Night: 1-800-424-9300
For Medical Emergencies Only, Call 1-877-325-1840

Date of Issue: May 17, 2012 **Supersedes:** February 23, 2007
Sections Revised: 3, 4, 7, 8, 11, 12, 13, 14, 15

2. HAZARDS IDENTIFICATION**Emergency Overview:**

Appearance and Odor: Brown colored granules with slight odor.

Warning Statements: Keep out of reach of children. CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing.

Potential Health Effects:

Likely Routes of Exposure: Inhalation, skin and eye contact.

Eye Contact: Moderately irritating based on toxicity studies. Dusts may cause irritation.

Skin Contact: Slightly toxic and minimally irritating based on toxicity studies.

Ingestion: Slightly toxic if ingested based on toxicity studies.

Inhalation: Low inhalation toxicity.

Medical Conditions Aggravated by Exposure: Inhalation of product may aggravate existing chronic respiratory problems such as asthma, emphysema or bronchitis. Skin contact may aggravate existing skin disease.

See Section 11: TOXICOLOGICAL INFORMATION for more information.

Potential Environmental Effects:

This product is highly toxic to aquatic invertebrates.

See Section 12: ECOLOGICAL INFORMATION for more information.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| COMPONENT | CAS NO. | % BY WEIGHT |
|---|-------------|-------------|
| Imidacloprid | 138261-41-3 | 0.5 |
| Other Ingredients including N-methyl pyrrolidone | 872-50-4 | 99.5 |

4. FIRST AID MEASURES

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Note to Physician: No specific antidote is available. Treat the patient symptomatically.

5. FIRE FIGHTING MEASURES

Flash Point: Not applicable

Autoignition Temperature: Not applicable **Flammability Limits:** Not applicable

Extinguishing Media: Use extinguishing media suitable for surrounding materials. Dry chemical, carbon dioxide, foam, water spray or fog.

Special Fire Fighting Procedures: Firefighters should wear NIOSH/MSHA approved self-contained breathing apparatus and full fire-fighting turn out gear. Dike area to prevent runoff and contamination of water sources. Dispose of fire control water later.

Unusual Fire and Explosion Hazards: If water is used to fight fire, contain runoff, using dikes to prevent contamination of water supplies. Dispose of fire control water later

Hazardous Decomposition Materials (Under Fire Conditions): May produce gases such as oxides of carbon and nitrogen.

National Fire Protection Association (NFPA) Hazard Rating:

Rating for this product: Health: 1 Flammability: 1 Reactivity: 0

Hazards Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate protective gear for the situation. See Personal Protection information in Section 8.

Environmental Precautions: Prevent material from entering public sewer systems or any waterways. Do not flush to drain. Large spills to soil or similar surfaces may necessitate removal of topsoil. The affected area should be removed and placed in an appropriate container for disposal.

Methods for Containment: Dike spill using absorbent or impervious materials such as earth, sand or clay. Collect and contain contaminated absorbent and dike material for disposal.

Methods for Cleanup and Disposal: Wash entire spill area with a detergent slurry, absorb and sweep into container for disposal. Decontaminate tools and equipment following cleanup. See Section 13: DISPOSAL CONSIDERATIONS for more information.

Other Information: Large spills may be reportable to the National Response Center (800-424-8802) and to state and/or local agencies.

7. HANDLING AND STORAGE

Handling:

Avoid contact with eyes or clothing. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove clothing/Personal Protective Equipment (PPE) if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Storage:

Store in a cool, dry place and in such a manner as to prevent cross-contamination with other pesticides, fertilizers, food and feed. Store in original container and out of reach of children, preferably in a locked storage area. Do not contaminate water, food or feed by storage or disposal.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:

Where engineering controls are indicated by specific use conditions or a potential for excessive exposure, use local exhaust ventilation at the point of generation.

Personal Protective Equipment:

Eye/Face Protection: To avoid contact with eyes, wear chemical goggles or shielded safety glasses. An emergency eyewash or water supply should be readily accessible to the work area.

Skin Protection: To avoid contact with skin, wear long pants, long-sleeved shirt, shoes plus socks, and chemical-resistant gloves made of waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton. An emergency shower or water supply should be readily accessible to the work area.

Respiratory Protection: Not normally required. If vapors or mists exceed acceptable levels, wear NIOSH approved air-purifying respirator with cartridges/canisters approved for use against pesticides.

General Hygiene Considerations: Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material: 1) do not store, use and/or consume foods, beverages, tobacco products, or cosmetics in areas where this material is stored; 2) wash hands and face carefully before eating, drinking, using tobacco, applying cosmetics or using the toilet.

Exposure Guidelines:

| Component | OSHA | | ACGIH | | Unit |
|--------------|------|------|-------|------|------|
| | TWA | STEL | TWA | STEL | |
| Imidacloprid | NE | NE | NE | NE | |

NE = Not Established

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: Brown colored granules with slight odor.

Boiling Point: Not applicable

Density: 46 pounds/cubic foot

Evaporation Rate: Not applicable

Freezing Point: Not applicable

pH: 6.4

Solubility in Water: Relatively insoluble

Specific Gravity: Not applicable

Vapor Density: Not applicable

Vapor Pressure: Not applicable

Viscosity: Not applicable

Note: Physical data are typical values, but may vary from sample to sample. A typical value should not be construed as a guaranteed analysis or as a specification.

10. STABILITY AND REACTIVITY

Chemical Stability: This material is stable under normal handling and storage conditions.

Conditions to Avoid: Excessive heat. Do not store near heat or flame.

Incompatible Materials: Strong oxidizing agents; bases and acids.

Hazardous Decomposition Products: Under fire conditions may produce gases such as oxides of carbon and nitrogen.

Hazardous Reactions: Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Toxicological Data:

Data from laboratory studies conducted on a similar, but not identical, formulation:

Oral: Rat LD₅₀: > 5,000 mg/kg (female)

Dermal: Rat LD₅₀: > 5,000 mg/kg

Inhalation: Rat 4-hr LC₅₀: >2.06 mg/l

Eye Irritation: Rabbit: Moderately irritating

Skin Irritation: Rabbit: Minimally irritating

Skin Sensitization: Not a contact sensitizer in guinea pigs following repeated skin exposure.

Subchronic (Target Organ) Effects: Repeated overexposure to imidacloprid, may affect heart, thyroid, blood chemistry, and liver. Repeated overexposure to N-Methyl 2-pyrrolidinone (NMP) may cause effects to eyes, skin, respiratory system, central nervous system, liver and kidneys. The solvent component of this product is reported to cause irritation to the eyes and skin and may contribute to the irritation potential reported for this product.

Carcinogenicity / Chronic Health Effects: Prolonged overexposure to imidacloprid can cause effects to the thyroid. Imidacloprid did not cause cancer in laboratory animal studies. The U.S. EPA has given imidacloprid a Group E classification (evidence of non-carcinogenicity in humans). No increase in tumors was seen in rats via dietary or inhalation exposure to NMP for two years; however, an increase in liver tumors was noted in mice receiving high dietary doses over a similar period. Liver tumors are not uncommon when non-genotoxic chemicals such as NMP are tested in the mouse bioassay.

Reproductive Toxicity: In a two-generation reproduction study in rats, imidacloprid produced reduced mean body weights and body weight gains. No other reproductive effects were observed. NMP may adversely affect reproduction in rats after ingestion, although fertility is unaltered.

Developmental Toxicity: Rat and rabbit studies on imidacloprid resulted in skeletal abnormalities, increased resorptions (rabbits) and reduced body weight gains at doses that were also toxic to mother animals. Fetal developmental effects were observed following ingestion, inhalation and dermal exposures to NMP in pregnant animals, and occurred both in the presence and absence of maternal toxicity.

Genotoxicity: The imidacloprid mutagenicity studies, taken collectively, demonstrate that imidacloprid is not genotoxic or mutagenic. Neither *in vitro* nor *in vivo* tests on NMP demonstrated mutagenic effects.

Assessment Carcinogenicity: None listed with ACGIH, IARC, NTP or OSHA.

See Section 2: HAZARDS IDENTIFICATION for more information.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Data on Imidacloprid Technical:

Data on Imidacloprid Technical:

| | | | |
|--|---------------|---|-----------|
| 96-hour LC ₅₀ Rainbow Trout: | 211 mg/l | Japanese Quail Oral LD ₅₀ : | 31 mg/kg |
| 48-hour EC ₅₀ Daphnia: | 85 mg/l | Bobwhite Quail Oral LD ₅₀ : | 152 mg/kg |
| 96-hour LC ₅₀ Mysid: | 0.038 ppm | House Sparrow Oral LD ₅₀ : | 41 mg/kg |
| 96-hour LC ₅₀ Bluegill: | >105 mg/l | Bobwhite Quail 8-day Dietary LC ₅₀ : | 1535 ppm |
| 48-hour Honey Bee Contact LD ₅₀ : | 0.078 µg/bee | Mallard Duck 8-day Dietary LC ₅₀ : | >4797 ppm |
| 48-hour Honey Bee Oral LD ₅₀ : | 0.0039 µg/bee | | |

Environmental Fate:

Hydrolysis half-life of imidacloprid is greater than 30 days at pH 7 and 25°C. The aqueous photolysis half-life is less than 3 hours. The soil surface photolysis of imidacloprid has a half-life of 39 days, and in soil, the half-life ranged from 26 to 229 days.

13. DISPOSAL CONSIDERATIONS**Waste Disposal Method:**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide is a violation of Federal law.

Container Handling and Disposal:

Nonrefillable bags: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinance. If burned stay out of smoke.

14. TRANSPORTATION INFORMATION

Follow the precautions indicated in Section 7: HANDLING AND STORAGE of this MSDS.

DOT

Not regulated by DOT unless shipped by water. See IMO / IMDG description.

IMDG

UN3077, Environmentally hazardous substance, solid, n.o.s.,
(Imidacloprid), 9, III, Marine Pollutant

IATA

UN3077, Environmentally hazardous substance, solid, n.o.s.,
(Imidacloprid), 9, III, Marine Pollutant

15. REGULATORY INFORMATION**U.S. Federal Regulations:**

TSCA Inventory: This product is exempted from TSCA because it is solely for FIFRA regulated use.

SARA Hazard Notification/Reporting:

Hazard Categories Under Criteria of SARA Title III Rules (40 CFR Part 370): Immediate

Section 313 Toxic Chemical(s):

N-Methyl-2-pyrrolidinone (CAS No 872-50-4), < 2% by weight in product

Reportable Quantity (RQ) under U.S. CERCLA: None

RCRA Waste Code: None

State Information:

Other state regulations may apply. Check individual state requirements.

California Proposition 65: WARNING. This product contains chemicals known to the State of California to cause cancer or birth defects or other reproductive harm

| |
|-----------------------|
| 16. OTHER INFORMATION |
|-----------------------|

This Material Safety Data Sheet (MSDS) serves different purposes than and DOES NOT REPLACE OR MODIFY THE EPA-ACCEPTED PRODUCT LABELING (attached to and accompanying the product container). This MSDS provides important health, safety and environmental information for employers, employees, emergency responders and others handling large quantities of the product in activities generally other than product use, while the labeling provides that information specifically for product use in the ordinary course.


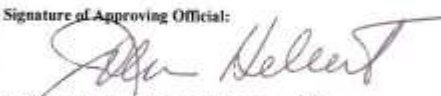
Use, storage and disposal of pesticide products are regulated by the EPA under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through the product labeling, and all necessary and appropriate precautionary, use, storage, and disposal information is set forth on that labeling. It is a violation of Federal law to use a pesticide product in any manner not prescribed on the EPA-accepted label.

Although the information and recommendations set forth herein (hereinafter "Information") are presented in good faith and believed to be correct as of the date hereof, Nufarm Americas Inc. makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Nufarm Americas Inc. be responsible for damages of any nature whatsoever resulting from the use of or reliance upon Information. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO INFORMATION OR THE PRODUCT TO WHICH INFORMATION REFERS.

Mallet is a registered trademark of Nufarm Americas Inc.

APPENDIX C. Protector 2F Formulation Label

APPENDIX

| | | |
|---|---|---|
|  <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Chemical Safety and Pollution Prevention Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under FIFRA, as amended)</p> | EPA Reg. Number: 88867-2 | Date of Issuance: JUN 06 2013 |
| | Term of Issuance: Conditional | |
| | Name of Pesticide Product: Protector 2F | |
| Name and Address of Registrant (include ZIP Code): Willapa-Grays Harbor Oyster Growers Association P.O. Box 3, Ocean Park, WA 98640 | | |
| <p><small>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</small></p> | | |
| <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This product is conditionally registered in accordance with FIFRA section 3(c)(7)(a). You must:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit such data. 2. Submit or cite any data which have previously been required for imidacloprid. 3. Make the following label change before you release the product for shipment: <ul style="list-style-type: none"> • Revise the EPA Registration Number to read, "EPA Reg. No 88867-2." | | |
| Signature of Approving Official:  John Hebert, Product Manager 07 Insecticide/Rodenticide Branch, Registration Division (7505P) | Date: JUN 06 2013 | |

EPA Form 3245-6

4. Note that monitoring data reporting is required under the National Pollutant Discharge Elimination System (NPDES) permit. We request that you submit this information to the Registration Division, Office of Pesticide Programs, as well.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the CSF currently on file for this product is the basic CSF, dated 2/21/12.

If you have any questions, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

ADP

GROUP **4A** INSECTICIDE

PROTECTOR 2F

FOR USE ONLY IN WILLAPA BAY/ GRAYS HARBOR, WASHINGTON,
TO CONTROL BURROWING SHRIMP IN COMMERCIAL SHELLFISH
BEDS

ACTIVE INGREDIENT:

Imidacloprid: 1-[(6-Chloro-3-pyridiny)methyl]-N-nitro-2-imidazolidinimine..... 21.4%

OTHER INGREDIENTS:..... 78.6%

TOTAL:.....100.0%

Contains 2 pounds of imidacloprid per gallon.

KEEP OUT OF REACH OF CHILDREN CAUTION-CAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No.

EPA Establishment No.

SHAKE WELL BEFORE USING

ACCEPTED
JUN 06 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA Reg. No.: 88867-2

| FIRST AID | |
|---|--|
| If swallowed: | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person. |
| If inhaled | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. |
| If on skin or clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice. |
| <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.</p> <p>NOTE TO PHYSICIAN</p> <p>No specific antidote is available. Treat the patient symptomatically.</p> | |

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if swallowed. Harmful if inhaled. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton
- Shoes and socks
- Protective eyewear

Follow Manufacturer's instructions for cleaning/maintaining PPE. If instructions for washables do not exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENTS
 When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

| USER SAFETY RECOMMENDATIONS | |
|-----------------------------|--|
| Users Must: | <ul style="list-style-type: none"> • Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. • Remove clothing immediately if pesticide gets inside. Wash contaminated area thoroughly and put on clean clothing. • Remove PPE immediately after handling this product. Wash the outside of gloves before removing. |

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops and weeds. Do not allow this product to drift to blooming crops or weeds are visiting the treatment area. This product is toxic to wildlife and highly toxic to aquatic invertebrates.

DIRECTIONS FOR USE

It is a violation of the Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time the product is applied.

READ THIS LABEL: Read the entire label and follow all use directions and precautions.

For use only to control burrowing shrimp in intertidal commercial shellfish beds of Washington State's Willapa Bay and Grays Harbor.

MIXING INSTRUCTIONS:

To prepare the application mixture, add a portion of the required amount of water to the spray tank, begin agitation, and add the Protector 2F. Complete filling tank with the balance of water needed. Be sure to maintain agitation during both mixing and application.

Do NOT formulate this product into other end-use products.

APPLICATION INSTRUCTIONS:

To control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor], apply at a maximum rate of 0.5 lb a.i. imidacloprid /acre per year using the following properly calibrated application equipment:

- Helicopters equipped with boom $\frac{1}{4}$ as long as rotor diameter equipped with Accuflo or similar nozzles
- Backpack sprayer.
- Ground based vehicle with boom.

RESTRICTIONS:

- Do not harvest shellfish within thirty days after treatment.
- All ground must be properly staked and flagged to protect adjacent shellfish and water areas. For aerial applications, the corners of each plot must be marked so the plot is visible from an altitude of at least 500ft.
- Aerial applications must be on beds exposed at low tide.
- A single application of imidacloprid per year is allowed.
- No adjuvants or surfactants are allowed with the use of this product.
- All applications must occur between April 15 and December 15.
- A 100-foot buffer zone must be maintained between the treatment area and the nearest shellfish to be harvested when treatment is by aerial spray; a 25 foot buffer zone is required if treatment is by hand spray.
- Do not apply aerially during Federal holiday weekends. During aerial applications, all public access areas within one-quarter (1/4) mile and all public boat launches within a quarter (1/4) mile radius of any bed scheduled for treatment shall be posted. Public access areas shall be posted at 500 foot intervals at those access areas more than 500 feet wide. Signs shall be a minimum of 8 1/2 x 11 inches in size, and be made of a durable

- weather-resistant, white material. The sign will say "Imidacloprid will be applied for burrowing shrimp control on [date] on commercial shell fish beds. Do not Fish, Crab or Clam within one-quarter mile of the treated area. The location of the treated area will be included on the sign.
- The sign will include lettering shall be in bold black type with the word "WARNING" or "CAUTION" at least one-fourth (1/4) of an inch high. Signs shall be posted so they are secure from the normal effects of weather and water currents, but cause no damage to private property. Signs shall be posted at least 2 days prior to treatment and shall remain for at least 30 days after treatment.

SPRAY DRIFT MANAGEMENT:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determines the potential for spray drift. The applicator and the entity authorizing spraying are responsible for considering all these factors when making decisions.

To minimize spray drift, the applicator should be familiar with and take into account the following drift reduction advisory information. Additional information may be available from state enforcement agencies or the Cooperative Extension on the application of the product.

The best drift management strategy and most effective way to reduce drift potential are to apply large droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see WIND, TEMPERATURE AND HUMIDITY, and TEMPERATURE INVERSIONS).

CONTROLLING DROPLET SIZE

- Volume – Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure – Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of Nozzles – Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Orientation – Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is recommended practice. Significant deflection from the horizontal will reduce droplet size and increase drift potential.
- Nozzle Type – Use a nozzle type that is designed for the intended application. With most nozzle types, narrow spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift. Do not use nozzles producing a mist droplet spray.

APPLICATION HEIGHT

Making applications at the lowest possible height (helicopter, ground driven spray boom) that is safe and practical reduces exposure of droplets to evaporation and wind. Swath adjustment distance should increase with increasing drift potential (higher wind, smaller droplets, etc.).

WIND

Drift potential is lowest between wind speeds of 3-10 mph. However, many factors, including droplet size and equipment type, determine drift potential at any given speed. Application should be avoided below 3 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE INVERSIONS

Drift potential is high during a temperature inversion. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud, which can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

AERIAL APPLICATION METHODS AND EQUIPMENT HELICOPTERS ONLY

Water Volume: Use 2 or more gallons of water per acre. The actual minimum spray volume per acre is determined by the spray equipment used. Use adequate spray volume to provide accurate and uniform distribution of spray particles over the treated area and to avoid spray drift.

Managing spray drift from aerial applications: Applicators must follow these requirements to avoid off-target drift movement: 1) boom length – the distance of the outmost nozzles on the boom must not exceed ¼ the length of the rotor, 2) nozzle orientation – nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees, and 3) application height – without compromising helicopter safety, applications should be made at a height of 10 feet or less above the crop canopy or tallest plants. Applicators must follow the most restrictive use cautions to avoid drift hazards, including those found in this labeling as well as applicable state and local regulations and ordinances.

GROUND APPLICATION (BROADCAST)

Water Volume: Use 5 or more gallons of water per acre. The actual minimum spray volume per acre is determined by the spray equipment used. Use adequate spray volume to provide accurate and uniform distribution of spray particles over the treated area and to avoid spray drift.

Spray tank should have constant agitation to assure adequate mixing of product.

AERIAL APPLICATIONS

All precautions should be taken to minimize or eliminate spray drift. Helicopters can be used to apply PROTECTOR 2F; however, DO NOT make applications by helicopter unless appropriate buffer zones can be maintained to prevent spray drift out of the target area, or when spray drift as a result of helicopter application can be tolerated. Aerial equipment designed to minimize spray drift, such as a helicopter

equipped designed to minimize spray drift, such as a helicopter equipped with a Microfoil™ boom, Thru-Valve™ boom or raindrop nozzles, must be used and calibrated. Except when applying with a Microfoil boom, a drift control agent may be added at the recommended label rate. To avoid drift, applications should not be made during inversion conditions, when winds are gusty or any other conditions which allow drift. Side trimming is not recommended with PROTECTOR 2F unless death of treated tree can be tolerated.

GROUND APPLICATIONS

Low Volume

Use equipment calibrated to deliver 5 to 20 gallons of spray solution per acre.

For low volume, selected proper nozzles to avoid over-application. Proper application is critical to ensure desirable results.

Restrictions During Temperature Inversions

Because the potential for spray drift is high during temperature inversions, do NOT make air applications during temperature inversions.

Mixing and Loading Requirements

The use of a properly designed and maintained containment pad for mixing and loading of any pesticide into application equipment is recommended. If containment pad is not used, maintain a minimum distance of 25 feet between mixing and loading areas and potential surface to groundwater conduits such as field sumps, uncased well heads, sinkholes, or field drains.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of reach of children, preferably in a locked storage area. Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides below. In spill or leak incidents, keep unauthorized people away.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of at an approved waste disposal facility.

CONTAINER DISPOSAL (HANDLING):

For containers smaller than 5 gallons: Nonrefillable container: Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Nonrefillable Containers Larger than 5 Gallons: Nonrefillable

container. Do not reuse or refill this container. Offer for recycling if available, Triple rinse or pressure rinse container (or equivalent) promptly after emptying.



Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

This product is registered by the Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640

APPENDIX D. Protector 0.5G Formulation Label

APPENDIX

| | | | |
|--|---|----------------------------|-------------------|
|  | <p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Chemical Safety and Pollution Prevention Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p> | EPA Reg. Number: | Date of Issuance: |
| <p align="center">NOTICE OF PESTICIDE: <u> X </u> Registration <u> </u> Reregistration</p> <p>(under FIFRA, as amended)</p> | | 88867-1 | JUN 06 2013 |
| | | Term of Issuance: | Conditional |
| | | Name of Pesticide Product: | Protector 0.5G |
| <p>Name and Address of Registrant (include ZIP Code): Willapa-Grays Harbor Oyster Growers Association P.O. Box 3, Ocean Park, WA 98640</p> | | | |
| <p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p> | | | |
| <p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> | | | |
| <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> | | | |
| <p>This product is conditionally registered in accordance with FIFRA section 3(c)(7)(a). You must:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration/registration review of your product when the Agency requires all registrants of similar products to submit such data. 2. Submit or cite any data which have previously been required for imidacloprid. 3. Make the following label change before you release the product for shipment: <ul style="list-style-type: none"> • Revise the EPA Registration Number to read, "EPA Reg. No 88867-1." | | | |
| <p>Signature of Approving Official:  John Hebert, Product Manager 07 Insecticide-Rodenticide Branch, Registration Division (7505P)</p> | | Date: | |
| EPA Form 8570-6 | | JUN 06 2013 | |

Page 2
EPA Reg. No. 88867-1

4. Note that monitoring data reporting is required under the National Pollutant Discharge Elimination System (NPDES) permit. We request that you submit this information to the Registration Division, Office of Pesticide Programs, as well.

5. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the CSF currently on file for this product is the basic CSF, dated 2/21/12.

If you have any questions, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Draft Label

ACCEPTED

JUN 06 2013

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

GROUP 4A INSECTICIDE

EPA Reg. No: 88867-1

PROTECTOR 0.5G

FOR USE ONLY IN WILLAPA BAY/ GRAYS HARBOR, WASHINGTON,
TO CONTROL BURROWING SHRIMP IN COMMERCIAL SHELLFISH
BEDS

ACTIVE INGREDIENT:

| | |
|---|--------|
| Imidacloprid: 1-[(6-Chloro-3-pyridiny) methyl]-N-nitro-2-imidazolidinimine..... | 0.5% |
| OTHER INGREDIENTS:..... | 99.5% |
| TOTAL:..... | 100.0% |

KEEP OUT OF REACH OF CHILDREN CAUTION-CAUCION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No.

EPA Establishment No.

| FIRST AID | |
|--|---|
| If in eyes: | <ul style="list-style-type: none"> Hold eye open and rise slowly and gently with water for 15-20 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. |
| <p>Have the product container or label with you when calling poison control center or doctor or going for treatment. You may also 1-800-222-1222 for emergency medical treatment information.</p> <p>NOTE TO PHYSICIAN</p> <p>No specific antidote is available. Treat the patient symptomatically.</p> | |

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton
- Shoes and socks
- Protective eyewear
- Dust mask

Follow manufacturer's instructions for cleaning/maintaining PPE. If instructions for washables do not exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS STATEMENTS

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users Must:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment wash waters. This product is toxic to wildlife and highly toxic to aquatic invertebrates.

DIRECTIONS FOR USE

It is a violation of the Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time the product is applied.

READ THIS LABEL: Read the entire label and follow all use directions and precautions.

For use only to control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor]

MIXING INSTRUCTIONS:

Do NOT formulate this product into other end-use products.

APPLICATION INSTRUCTIONS:

To control burrowing shrimp in intertidal commercial shellfish beds [of Washington State's Willapa Bay and Grays Harbor], apply at a maximum rate of 0.5 lb a.i. imidacloprid/acre per year.

Apply this product uniformly over the area being treated using drop-type or rotary-type spreaders. Do not use spreaders that would apply the material in narrow, concentrated bands. All spreader equipment must be calibrated at the time of application to achieve desired application rate.

Use one of the following properly calibrated application equipment:

- Conventional granular pesticide applicators ("belly grinders").
- Helicopters equipped with boom $\frac{1}{4}$ as long as rotor diameter.
- Ground based vehicles equipped with spinners or drop spreaders.

RESTRICTIONS:

- Do not harvest shellfish within 30 days after treatment.
- All ground must be properly staked and flagged to protect adjacent shellfish and water areas. For aerial applications, the corners of each plot must be marked so the plot is visible from an altitude of at least 500ft.
- A single application of imidacloprid at up to 0.5 ai per acre per year is allowed.
- No adjuvants or surfactants are allowed with the use of this product.
- Aerial applications must be on beds exposed at low tide. Applications from a floating platform or boat may be applied to beds under water using a calibrated granular applicator.
- All applications must occur between April 15 and December 15.
- A 100-foot buffer zone must be maintained between the treatment area and the nearest shellfish to be harvested within 30 days when treatment is by aerial spray; a 25 foot buffer zone is required if treatment is by hand spray if nearest shellfish bed is to be harvested within 30 days.
- Do not apply aerially during Federal holiday weekends. During aerial applications, all public access areas within one-quarter (1/4) mile and all public boat launches within quarter (1/4) mile radius of any bed scheduled for treatment shall be posted. Public access areas shall be posted at 500 foot intervals at those access areas more than 500 feet wide. Signs shall be a minimum of 8 1/2 x 11 inches in size, and be made of a durable weather-resistant, white material. The sign will say "Imidacloprid will be applied for burrowing shrimp control on [date] on commercial shellfish beds. Do not Fish, Crab or Clam within one-quarter mile of the treated area." The location of the treated area will be included on the sign.

Draft Label

The sign will include lettering shall be in bold black type with the word "WARNING" or "CAUTION" at least one-fourth (1/4) of an inch high. Signs shall be posted so they are secure from the normal effects of weather and water currents, but cause no damage to private property. Signs shall be posted at least 2 days prior to treatment and shall remain for at least 30 days after treatment.

This product is registered by the Willapa-Grays Harbor Oyster Growers Association, P.O. Box 3, Ocean Park, WA 98640

DRIFT MANAGEMENT:

The interaction of many equipment and weather related factors determine the potential for product drift. Average wind speed at the time of application is not to exceed 10 mph to minimize drift to adjacent shellfish and water areas when applied by air. Drift potential increases at wind speeds of less than 3 mph (due to inversion potential) or more than 10 mph. However, many factors including height of granular spreader above the tideflat and equipment specifications determine drift potential at any given wind speed. Do NOT apply when winds are greater than 10 mph or during temperature inversions. Make applications at the lowest possible height (helicopter, ground or barge) that is safe to operate and reduces exposure of the granules to wind. When applications are made crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the treatment area, the applicator must compensate for this displacement by adjusting the path of the application equipment upwind. Swath adjustment distance should increase with increasing drift potential.

Mixing and Loading Requirements

The use of a properly designed and maintained containment pad for mixing and loading of any pesticide into application equipment is recommended. If containment pad is not used, maintain a minimum distance of 25 feet between mixing and loading areas and potential surface to groundwater conduits such as field sumps, uncased well heads, sinkholes, or field drains.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide Storage: Store in a cool, dry place in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If material is spilled for any reason or cause, carefully contain any spilled material to prevent non-target contamination. Do not walk through spilled material and dispose of as directed for pesticides above. Refer to Precautionary Statements on label for hazards associated with handle of this material. In spill or leak incidents, keep unauthorized people away. For chemical spill, leak, fire, or exposure, you may contact CHEMTREC at 800-424-9300.

Container Disposal: Non-Refillable: Do not reuse or refill this container. Completely empty bag into application equipment. Dispose of empty bag in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

APPENDIX E. Human Health Incident Reports

APPENDIX

IDS Report

DATE: 8/27/2008

Chemical: Imidacloprid

129099

Human Incidents

| Incident Number | | Incident Date | Product Name | Registration Number | City | State | Exposure Type* | Incident Description |
|-----------------|-----|---------------|---|---------------------|------------------|-------|----------------|--|
| 009863 | 002 | 15-Jan-00 | ADVANTAGE (NON-SPECIFIC) | | ROCKFORD | IL | HC | A 41 year old Female reported Rash and Dermatitis |
| 009863 | 003 | 18-Jan-00 | ADVANTAGE 10 | 01155600117 | COCHRANVILLE | PA | HC | A 20 year old Male reported Shortness of Breath, Rash, Hives/Welts |
| 009863 | 004 | 21-Jan-00 | ADVANTAGE 100 | 01155600122 | | CA | HC | A 51 year old Female reported Bullae/Blisters, Dermal Irritation/Pain |
| 009981 | 001 | 15-Feb-00 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | RICHARDSON | TX | HC | A 49 year old Female reported Hives/Welts |
| 009981 | 002 | 09-Feb-00 | ADVANTAGE 20 | 01155600119 | MERRITT ISLAND | FL | HC | Unknown Adult (18-64 years old) Female reported Edema, Ocular Irritation/Pain, Redness, Blurred Vision |
| 009981 | 003 | 18-Feb-00 | ADVANTAGE 10 | 01155600116 | QUINLAN | TX | HC | A 2 year old Female Child reported Vomiting, Diarrhea |
| 009981 | 004 | 29-Feb-00 | ADVANTAGE 100 | 01155600122 | LA HABRA | CA | HC | A 17 year Male reported Hives/Welts, Pruritus |
| 010093 | 002 | 01-Jan-00 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | FAYETTEVILLE | NC | HC | A 20 year old Male reported Sensations of Pin and Needle Pricks, Joint Pain |
| 010093 | 004 | 01-Jan-00 | PREMISE 75 WP | 00312500455 | MESA | AZ | HC | Unknown Adult (18-64 years old) Male reported Blood Clots on Lungs |
| 010093 | 005 | 13-Jan-00 | ADVANTAGE 10 LIQUID | 01155600117 | ANAHEIM | CA | HC | A 14 year old Male reported Hives/Welts |
| 010210 | 008 | 01-Jan-00 | ADVANTAGE | | HUNTINGTON BEACH | CA | HC | A 11 year old Female reported Skin Redness/Flushed, Itching, |
| | | | | | | | | Rash |
| 010349 | 004 | 01-Mar-00 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | JACKSON | MI | HC | A 49 year old Female reported Nausea, Diarrhea |
| 010349 | 006 | 07-May-00 | ADVANTAGE 20 | 01155600119 | WINWOOD | OK | HC | A 47 year old Female reported Swelling, Hives/Welts, Headache, Difficulty Breathing, Pain |
| 010349 | 007 | 10-May-00 | ADVANTAGE 55 | 01155600120 | NIAGARA FALLS | NY | HC | A 15 year old Female reported Swelling, Redness of Skin/Flushed, Hives/Welts |
| 010349 | 008 | 16-May-00 | ADVANTAGE | | OVERLAND PARK | KS | HC | A 45 year old Female reported Asthma Attack |
| 010460 | 013 | 30-May-00 | ADVANTAGE 10 | 01155600117 | NORTH HAMPTON | MA | HC | Unknown Adult (18-64 years old) Female reported Swelling, Skin Red/Flushed, Hives/Welts, Itching, Rash |
| 010460 | 014 | 23-May-00 | ADVANTAGE | | NEPEAN, CANADA | ZZ | HC | A 41 year old Female reported Hives/Welts, Rash |
| 010460 | 015 | 19-May-00 | ADVANTAGE 9 | 01155600116 | PASADENA | CA | HC | A 42 year old Female reported Asthma Attacks |
| 010460 | 016 | 22-Jun-00 | ADVANTAGE 20 | 01155600119 | LENEXA | KS | HC | A 3 year old Male child reported Swelling, Seizure (single) |
| 010460 | 017 | 27-Jun-00 | ADVANTAGE 20 | 01155600119 | NEW SMYRNA BEACH | FL | HC | A 48 year old Male reported Hives/Welts, Itching |
| 010585 | 005 | 01-Jan-00 | ADVANTAGE (NON-SPECIFIC) | | WILMINGTON | DE | HC | A 2 month old Male Child reported Hemoglobinuria |

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| | | | | | | | | (blood disorder) |
| 010585 | 006 | 12-Jul-00 | ADVANTAGE 100 | 01155600122 | LAKE VIEW | NY | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Itching |
| 010682 | 002 | 01-May-00 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | ST. LOUIS | MO | HC | Unknown Adult (18-64 years old) Female reported Jaw Pain, Swelling, Infected salivary gland |
| 010682 | 006 | 01-Jul-00 | ADVANTAGE 9 | 01155600116 | SLIDELL | LA | HC | A 61 year old Male reported Itching, Rash |
| 010682 | 007 | 02-Aug-00 | ADVANTAGE 20 | 01155600119 | TULSA | OK | HC | A 47 year old Female reported Swelling, Hives/Welts |
| 010682 | 008 | 01-Aug-00 | ADVANTAGE 18 | 01155600118 | LOS ANGELES | CA | HC | A 46 year old Female reported Blisters, Skin Irritation/Pain |
| 010682 | 009 | 23-Aug-00 | ADVANTAGE 9 | 01155600116 | GREENS FORK | IN | HC | Unknown Adult (18-64 years old) Female reported Skin Irritation/Pain, Skin Redness/Flushed, Hives/Welts |
| 010787 | 004 | 01-Jun-00 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | UNIONTOWN | PA | HC | A 58 year old Male reported Loss of Appetite, Weight loss, Drowsiness/Lethargy, Tremor, Coughing/Choking |
| 010787 | 006 | 10-Sep-00 | ADVANTAGE 20 | 01155600119 | BOARDMAN | OH | HC | A 37 year old Female reported Rash |
| 010787 | 007 | 21-Sep-00 | ADVANTAGE 20 | 01155600119 | WARNERSVILLE | PA | HC | A 8 year old Female reported Rash On Entire Body Area |
| 010787 | 008 | 20-Sep-00 | ADVANTAGE 9 | 01155600116 | EMPORIUM | PA | HC | A 8 year old Female reported |

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| | | | | | | | | Rash, Lesions |
| 010787 | 009 | 01-Aug-00 | ADVANTAGE | | MARION | IN | HC | A 75 year old Female reported Swelling, Itching, Rash, Lesions |
| 010882 | 002 | 01-May-00 | PREMISE | | STANDFORD | KY | HC | A 65 year old Female reported Hives/Welts, Rash |
| 010882 | 005 | 09-Oct-00 | ADVANTAGE 55 | 01155600120 | HENDERSON | MD | HC | A 38 year old Male reported Swelling, Rash |
| 010967 | 004 | 22-Oct-00 | ADVANTAGE 18 | 01155600118 | LOS ANGELES | AL | HC | A 48 year old Female reported Itching, Rash on Thighs, Stomach, Back and Chest |
| 010967 | 005 | 07-Oct-00 | ADVANTAGE (NON-SPECIFIC) | | VALLEY GROVE | WV | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Pruritus |
| 010967 | 006 | 07-Nov-00 | ADVANTAGE 10 | 01155600117 | REDONDO BEACH | CA | HC | Unknown Adult (18-64 years old) Male reported Bullae/Blisters, Edema |
| 010967 | 007 | 08-Nov-00 | ADVANTAGE 10 | 01155600117 | PALM BAY | FL | HC | A 35 year old Female reported Blisters, Itching, Open Sores on Bottom Lip |
| 010967 | 008 | 02-Nov-00 | ADVANTAGE 9 | 01155600116 | CICERO | NY | HC | A 4 year old Female reported Skin Irritation/Pain, Swelling, Redness/Flushed, Respiratory Irritation |
| 010967 | 009 | 20-Aug-00 | ADVANTAGE 10 | 01155600117 | SAN FRANCISCO | CA | HC | Unknown Adult (18-64 years old) Female reported Ear Infection |
| 011064 | 005 | 29-Nov-00 | ADVANTAGE 20 | 01155600119 | BALA CYNWYD | PA | HC | A 52 year old Female reported Hives/Welts |
| 011064 | 006 | 26-Nov-00 | ADVANTAGE 10 | 01155600117 | HIGH SPRINGS | FL | HC | A 50 year old Female reported Blisters, Skin Irritation/Pain, Red Skin/Flushed, Hives/Welts, Itching, Rash |
| 011064 | 007 | 30-Nov-00 | ADVANTAGE 55 | 01155600120 | PACIFIC PALISADES | CA | HC | Unknown Adult (18-64 years old) Female reported Pain (Not Dermal, Gastrointestinal, Ocular) |
| 011064 | 008 | 16-Dec-00 | ADVANTAGE 20 | 01155600119 | HOUSTON | TX | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Itching, Rash |
| 011064 | 009 | 01-Dec-00 | ADVANTAGE 18 | 01155600118 | SACRAMENTO | CA | HC | A 54 year old Female reported Hives/Welts |
| 011176 | 002 | 25-Jan-01 | PREMISE (NON-SPECIFIC) | | PONTE VERDE | CA | HC | Unknown Adult (18-64 years old) Female reported Swelling, Hives/Welts, Itching, Muscle weakness |
| 011176 | 003 | 01-Apr-00 | PREMISE 75 INSECTICIDE | 00312500455 | WELLINGTON | MA | HC | Unknown Adult (18-64 years old) Male reported Abdominal pain, Throat Irritation, Respiratory Irritation |
| 011176 | 004 | 01-May-00 | ADVANTAGE 100 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600122 | BISHOPVILLE | SC | HC | A 45 year old Male reported Hives/Welts, Itching, Rash |
| 011176 | 006 | 05-Jan-01 | ADVANTAGE 55 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600120 | BIRMINGHAM | AL | HC | A 59 year old Female reported Loss of Taste |

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| 011176 | 007 | 04-Jan-01 | ADVANTAGE (NON-SPECIFIC) | | SANTA ANNA | CA | HC | A 58 year old Female reported Bullae/Blister, Erythema/Flushed, Itching, Rash, Skin Irritation/Pain, Erythema/Flushed, Hives/Welts, Itching |
| 011176 | 008 | 20-Jan-01 | ADVANTAGE 55 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600120 | ORLANDO | FL | HC | A 2 year old Male Child reported Respiratory Irritation, Wheezing |
| 011269 | 002 | 20-Feb-01 | ADVANTAGE 10 | 01155600117 | TIBURON | CA | HC | A 46 year old Female reported Itching, Small Skin Bumps |
| 011269 | 003 | 23-Feb-01 | ADVANTAGE 55 | 01155600120 | TARPON SPRINGS | FL | HC | Unknown Adult (18-64 years old) Male reported Swelling, Hives/Welts |
| 011380 | 002 | 13-Jan-01 | PREMISE | | BLYTHEVILLE | AR | HC | A 43 year old Female reported Throat Irritation, Headache, Upper Respiratory Infection, Sinus Infection |
| 011380 | 004 | 01-Jan-01 | ADVANTAGE 20 | 01155600119 | SNELLVILLE | GA | HC | A 34 year old Male reported Hives/Welts, Itching, Rash |
| 011380 | 005 | 03-Mar-01 | ADVANTAGE 100 | 01155600122 | ARMOND BEACH | FL | HC | A 53 year old Female reported Eye Irritation/Pain, Redness, Swelling, Eye Infection in Both Eyes |
| 011380 | 006 | 01-Feb-01 | ADVANTAGE 20 | 01155600119 | CLEARWATER | FL | HC | Unknown Adult (18-64 years old) Male reported Skin Irritation/Pain, Redness/Flushed |
| 011380 | 007 | 03-Mar-01 | ADVANTAGE 55 | 01155600120 | KNOXVILLE | TN | HC | A 29 year old Female reported Hives/Welts, Itchy Hands, Head, Arms and Legs |
| 011508 | 004 | 09-Apr-01 | PREMISE (NON-SPECIFIC) | | OKLAHOMA CITY | OK | HC | A 40 year old Female reported Swelling, Painful Skin, Swollen Joints, Drowsiness/Lethargy, Muscle weakness, Fever/Hyperthermia, Pain (not Dermal, Gastrointestinal, Ocular) |
| 011508 | 005 | 17-Apr-01 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | HAGERSTOWN | MD | HC | A 40 year old Female reported Erythema/Flushed, Hives/Welts, Itching, Rash |
| 011508 | 007 | 31-Mar-01 | ADVANTAGE 55 | 01155600120 | GLASGOW | KY | HC | A 40 year old Male reported Hives/Welts, Itching |
| 011508 | 008 | 01-Mar-01 | ADVANTAGE 55 | 01155600120 | CLAIRMONT | FL | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Itching, Rash |
| 011508 | 009 | 05-Apr-01 | ADVANTAGE (NON-SPECIFIC) | | ERIE | PA | HC | A 31 year old Female reported Dermal Irritation/Pain, Hives/Welts, Itching, Shortness of Breath, Swelling |
| 011508 | 010 | 08-Apr-01 | ADVANTAGE 10 | 01155600117 | SNOHOMISH | WA | HC | A 57 year old Female reported Dermal Irritation/Pain, Hives/Welts, Itching |
| 011508 | 011 | 13-Apr-01 | ADVANTAGE 10 | 01155600117 | BRONX | NY | HC | A 27 year old Female reported Color Alteration, Itching |
| 011508 | 012 | 01-Oct-00 | ADVANTAGE 9 | 01155600116 | AUSTIN | TX | HC | A 57 year old Female reported Numbness in Arms |
| 011508 | 013 | 04-Apr-01 | ADVANTAGE 100 | 01155600122 | COMPTON | CA | HC | A 85 year old Female reported Possible Seizure Activity, Visual Defect |
| 011508 | 014 | 23-Mar-01 | ADVANTAGE (NON-SPECIFIC) | | | VA | HC | A 18 year old Female reported Low White Blood Count and Bone Marrow |
| 011508 | 015 | 24-Apr-01 | ADVANTAGE (NON-SPECIFIC) | | LONG BEACH | CA | HC | A 70 year old Female reported Fainting |
| 011508 | 016 | 26-Apr-01 | ADVANTAGE 18 | 01155600118 | WENDELL | NC | HC | A 69 year old Female reported Dermal Irritation/Pain, Itching, Rash |
| 011662 | 008 | 24-May-01 | SEASON LONG GRUB CONTROL GRANULES | 00312500508 072155 | HIGH RIDGE | MO | HC | A 5 year old Female reported Blue Lips, Shortness of breath |
| 011662 | 010 | 01-Apr-01 | ADVANTAGE (NON-SPECIFIC) | | MARION | IN | HC | Unknown Adult (18-64 years old) Female reported Tingling, Drowsiness/Lethargy, Peripheral Neuropathy |
| 011662 | 011 | 30-Apr-01 | ADVANTAGE 20 | 01155600119 | ROCHESTER | NH | HC | A 65 year old Female reported Hives/Welts, Skin Redness/Flushed |
| 011662 | 012 | 03-Apr-01 | ADVANTAGE 55 | 01155600120 | BIXBY | OK | HC | A 26 year old Male reported Hives/Welts |
| 011662 | 013 | 17-Apr-01 | ADVANTAGE 9 | 01155600116 | ALLIANCE | OH | HC | A 63 year old Male reported Dermal Irritation/Pain, Skin Redness/Flushed |
| 011814 | 004 | 26-Apr-01 | MARATHON 1 % GRANULAR GREENHOUSE AND NURSERY INSECTICIDE | 00312500452 059807 | | GA | HC | A 18 year old Female reported Increased Liver Function Tests |

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| 011814 | 005 | 25-Jun-01 | PREMISE 75 INSECTICIDE | 00312500455 | DAVENPORT | IA | HB | A 40 year old Male reported Dizziness/Vertigo, Malaise, Multiple Sclerosis |
| 011814 | 018 | 05-Jun-01 | ADVANTAGE 9 | 01155600116 | NATIONAL CITY | CA | HC | Unknown Adult (18-64 years old) Male reported Chest Pain (including non-heart related) |
| 011814 | 019 | 09-Jun-01 | ADVANTAGE 9 | 01155600116 | BELLVIEW | FL | HC | A 47 year old Female reported Irritation/Pain, Swollen Eyelids, Redness, Burns, |
| 011814 | 021 | 09-Jun-01 | ADVANTAGE 100 | 01155600122 | BATON ROUGE | LA | HC | Unknown Adult (18-64 years old) Male reported Skin Redness/Flushed, Irritation/Pain, Rash |
| 011814 | 022 | 08-Jun-01 | ADVANTAGE 20 | 01155600119 | WETUMPKA | AL | HC | A 35 Year old Female reported Itching, Rash, Skin Redness/Flushed |
| 011814 | 023 | 28-May-01 | ADVANTAGE | | CANADA | ZZ | HC | A 38 year old Male reported Shortness of Breath |
| 011970 | 019 | 10-Jul-01 | ADVANTAGE 18 | 01155600118 | LITCHFIELD | KY | HC | A 37 year old Male reported Swelling, Hives/Welts |
| 011970 | 020 | 11-Jul-01 | ADVANTAGE 55 | 01155600120 | SAN JOSE | CA | HC | A 31 year old Female reported Irritation/Pain, Numbness |
| 011970 | 021 | 09-Jul-01 | ADVANTAGE | | INVERNESS | FL | HC | A 6 year old Female reported Rash, Itching on Thighs and Upper Legs |
| 011970 | 022 | 10-Jun-01 | ADVANTAGE 18 | 01155600118 | FAIRPORT | NY | HC | A 57 year old Female reported Muscle Control Difficulty, Dizziness/Vertigo |
| 011970 | 024 | 29-Jun-01 | ADVANTAGE 10 | 01155600117 | AUSTIN | TX | HC | A 18 year old Female reported Hives/Welts |
| 012071 | 008 | 03-May-01 | ADVANTAGE | | D CITY | FL | HC | A 75 year old Female reported Irritation/Pain, Rash |
| 012071 | 010 | 30-Jul-01 | ADVANTAGE 55 | 01155600120 | SEMINOLE | FL | HC | Unknown Adult (18-64 years old) Male reported Rash, Swelling, Itching, Hives/Welts |
| 012071 | 011 | 03-Aug-01 | ADVANTAGE 9 | 01155600116 | MONTGOMERY | AL | HC | A 30 year old Male reported Hives/Welts |
| 012071 | 012 | 12-Aug-01 | ADVANTAGE 9 | 01155600116 | JORDAN | NY | HC | Unknown Adult (18-64 years old) Female reported Bullae/Blisters, Itching |
| 012071 | 013 | 13-Aug-01 | ADVANTAGE 55 | 01155600120 | TIGARD | OR | HC | A 29 year old Female reported Hives/Welts, Itching |
| 012071 | 014 | 01-May-01 | ADVANTAGE | | HAMPTON | VA | HC | A 52 year old Female reported Itching, Irritation/Pain, Rash |
| 012177 | 007 | 01-Sep-01 | ADVANTAGE (NON-SPECIFIC) | | WOODLAND | PA | HC | A 31 year old Female reported Rash, Itching, Hives/Welts |
| 012177 | 008 | 05-Sep-01 | ADVANTAGE (NON-SPECIFIC) | | MILTON | KY | HC | A 23 month old Male reported Coughing/choking |
| 012177 | 009 | 11-Sep-01 | ADVANTAGE (NON-SPECIFIC) | | SOUTHBRIDGE | MA | HC | A 60 year old Female reported Hives/Welts, Itching, Swollen Throat |
| 012177 | 010 | 14-Jul-01 | ADVANTAGE 9 | 01155600116 | TAYLORSVILLE | NC | HC | A 69 year old Female reported Itching, Rash, Blisters |
| 012177 | 011 | 01-Jan-01 | ADVANTAGE (NON-SPECIFIC) | | DALLAS | TX | HC | Unknown Adult (18-64 years old) Female reported Dizziness/Vertigo, Oral Irritation |
| 012177 | 012 | 20-Sep-01 | ADVANTAGE 9 | 01155600116 | GAINESVILLE | GA | HC | A 36 year old Female reported Hives/Welts, Swelling, Itching |
| 012177 | 013 | 01-Jan-01 | ADVANTAGE (NON-SPECIFIC) | | DETROIT | MI | HC | A 33 year old Female reported Hypotension |
| 012255 | 001 | 26-Sep-01 | MERIT 75 WSP INSECTICIDE | 00312500439 | | WA | HC | A 58 year old Male reported Chest Pain |
| 012255 | 008 | 17-Sep-01 | ADVANTAGE 18 | 01155600118 | SADSBURYVILLE | PA | HC | Unknown Adult (18-64 years old) Male reported Irritation/Pain, Redness, Bacterial Infection |
| 012255 | 009 | 30-Sep-01 | ADVANTAGE 20 | 01155600119 | KALAMAZOO | MI | HC | A 47 year old Female reported Itching, Rash on Face |
| 012255 | 010 | 05-Oct-01 | ADVANTAGE 18 | 01155600118 | CAPE MAY | NJ | HC | Unknown Adult (18-64 years old) Female reported Irritation/Pain, Swelling |
| 012255 | 012 | 22-Jun-01 | ADVANTAGE 18 | 01155600118 | ISELIN | NJ | HC | A 50 year old Female reported Lip and Eyelid Swelling |
| 012255 | 013 | 30-Oct-01 | ADVANTAGE 9 | 01155600116 | HOLIDAY | FL | HC | A 78 year old Female reported Rash on Abdomen and Back |
| 012306 | 001 | 18-Nov-01 | MARATHON 2 GREENHOUSE AND NURSERY INSECTIDE | 00312500549 059807 | E. PROVIDENCE | RI | HC | Unknown Adult (18-64 years old) Male reported Hives/Welts |
| 012306 | 003 | 01-Nov-01 | ADVANTAGE 55 | 01155600120 | ATHENS | GA | HC | A 62 year old Female reported Hives/Welts, Itching, Rash, Eczema |
| 012306 | 004 | 20-Oct-01 | ADVANTAGE 20 | 01155600119 | POTTSTOWN | PA | HC | A 33 year old Female reported Itching Hives/Welts, Chest Pain |
| 012306 | 005 | 29-Oct-01 | ADVANTAGE 9 | 01155600116 | QUINCY | MA | HC | Unknown Adult (18-64 years old) Female reported |

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| | | | | | | | | Hives/Welts, Itching |
| 012465 | 002 | 10-Nov-01 | ADVANTAGE 20 | 01155600119 | MODESTO | CA | HC | A 7 year old Female reported Hives/Welts, Shortness of Breath, Difficulty breathing, Swelling |
| 012465 | 003 | 26-Nov-01 | ADVANTAGE 9 | 01155600116 | BEVERLY HILLS | CA | HC | A 45 year old Female reported Irritation/Pain, Contusion |
| 012465 | 004 | 01-Sep-00 | ADVANTAGE 55 | 01155600120 | BAINBRIDGE ISLAND | WA | HC | A 30 year old Female reported Rash, Itching, Joint Pain |
| 012465 | 005 | 19-Dec-01 | ADVANTAGE 55 | 01155600120 | EAST MILSBOROUGH | PA | HC | A 48 year old Female reported Hives/Welts, Swelling, Itching |
| 012465 | 006 | 16-Dec-01 | ADVANTAGE 9 | 01155600116 | AUSTIN | TX | HC | A 52 year old Male reported Hives/Welts, Irritation/Pain, Itching, Skin Redness/Flushed |
| 012465 | 007 | 26-Nov-01 | ADVANTAGE (NON-SPECIFIC) | | NASHVILLE | TN | HC | A 31 year old Female reported Rash On Entire Body Area |
| 012465 | 008 | 24-Dec-01 | ADVANTAGE 9 | 01155600116 | ROCHESTER | NY | HC | Unknown Adult (18-64 years old) Female reported Rash on Abdomen and Back of Legs |
| 012574 | 002 | 07-Oct-01 | ADVANTAGE 55 | 01155600120 | CLAREMONT | CA | HC | Unknown Adult (18-65) Male reported Dizziness/Vertigo, Hearing Loss and Vomiting |
| 012574 | 003 | 17-Jan-02 | ADVANTAGE 55 | 01155600120 | PAYLESS HEIGHTS | IL | HC | A 4 year old Male child reported Hives and Welts |
| 012693 | 002 | 01-Jan-02 | ADVANTAGE 10 | 01155600117 | CHAPEL HILL | NC | HB | A 79 year old Male reported Visual Defect |
| 012693 | 003 | 28-Jan-02 | ADVANTAGE 18 | 01155600118 | COLUMBIA | SC | HC | A 43 year old Female reported Skin Redness/Flushed, Coughing/Choking and Difficulty Breathing |
| 012693 | 004 | 12-Feb-02 | ADVANTAGE 20 | 01155600119 | NAPONA | CA | HC | Unknown Adult (18-64 years old) Female reported Bronchial Infection and Throat Irritation |
| 012759 | 001 | 11-Feb-02 | PREMISE (NON-SPECIFIC) | | | CA | HC | Unknown Adult (18-64 years old) Female reported Numbness, Joint Pain, Lacrimation and Edema |
| 012759 | 004 | 02-Mar-02 | ADVANTAGE 9 | 01155600116 | HOUSTON | TX | HC | A 38 year old Female reported Itching, Hives/Welts, Swelling |
| 012869 | 001 | 22-Apr-02 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | | FL | HC | A 25 year old Male reported Punctured Wound |
| 012869 | 005 | 13-Apr-02 | 3-IN 1 ROSE & FLOWER POTTING MIX (NON-SPECIFIC) | 00312500532 072155 | | NC | HC | A 9 year old Female reported Itching and Rash |
| 012869 | 006 | 24-Apr-02 | 2-IN-1 PLANT SPIKES | 00312500531 072155 | | AZ | HC | A 14 year old Male reported Bullae/Blisters |
| 012869 | 007 | 04-Apr-02 | ADVANTAGE 100 | 01155600122 | NEW FOUNDLAND | PA | HC | Unknown Adult (18-64 years old) Female reported Dizziness/Vertigo |
| 012869 | 008 | 09-Apr-02 | ADVANTAGE 10 | 01155600117 | ROSEVILLE | MI | HC | Unknown Adult (18-64 years old) Female reported Swelling, Bullae/Blisters, Teary Eye, Irritation/Pain |
| 012869 | 009 | 06-Apr-02 | ADVANTAGE 100 | 01155600122 | HAYWARD | CA | HC | Unknown Adult (18-64 years old) Female reported Dry Skin |
| 012869 | 011 | 30-Mar-02 | ADVANTAGE 100 | 01155600122 | LOS ANGELES | CA | HC | Unknown Adult (18-64 years old) Female reported Itching and Bullae/Blisters |
| 012982 | 001 | 30-Apr-02 | MERIT 75 WP INSECTICIDE | 00312500421 | PHILLY | PA | HC | A 49 year old Male reported Coughing/Choking and Confusion |
| 012982 | 016 | 02-May-02 | ADVANTAGE (NON-SPECIFIC) | | | HI | HC | Unknown Adult (18-64) Female reported Hives/Welts, Itching |
| 012982 | 017 | 06-May-02 | ADVANTAGE 55 | 01155600120 | ROUSVILLE | PA | HC | A 9 year old Male reported Rash, Itching, Swelling |
| 012982 | 018 | 14-May-02 | ADVANTAGE 10 | 01155600117 | PARAMOUNT | CA | HC | A 38 year old Male reported Swelling |
| 012982 | 020 | 14-May-02 | ADVANTAGE (NON-SPECIFIC) | | LAKEWOOD | CA | HC | Unknown Adult (18-64 year old) Male reported Swelling |
| 012982 | 023 | 27-May-02 | ADVANTAGE 10 | 01155600117 | VALLEJO | CA | HC | Unknown Adult (18-64 years old) Female reported Rash |
| 013092 | 001 | 07-Jun-02 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | BORGER | TX | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Rash, Itching |
| 013092 | 002 | 01-Jun-00 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | | WV | HC | Unknown Female reported Hoarseness, Headache, Throat Tightness, Lethargy |
| 013092 | 003 | 03-Jun-02 | PREMISE 2 INSECTICIDE | 00312500454 | CANTON | OH | HC | Unknown Adult (18-64 years old) Male reported Irritation/Pain and Eye Irritation |
| 013092 | 014 | 31-May-02 | ADVANTAGE (NON-SPECIFIC) | | KNOXVILLE | TN | HC | Unknown Adult (18-64 years old) Female reported Accelerated Heart Rate |

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| 013092 | 015 | 03-Jun-02 | ADVANTAGE 10 | 01155600117 | PALM COAST | FL | HC | A 5 year old Female reported Swelling, Blotchy skin, Fever/Hyperthermia |
| 013092 | 016 | 06-Jun-02 | ADVANTAGE 9 | 01155600116 | KINGWOOD | TX | HC | A 22 year old Female reported Swelling, Itching, Rash |
| 013092 | 017 | 27-Jun-02 | ADVANTAGE 10 | 01155600117 | TACOMA | WA | HC | A 3 year old Female Child reported Hives/Welts, Itching |
| 013218 | 014 | 17-Jul-02 | 3-IN-1 MULTI-PURPOSE POTTING MIX (10 QT) | 00312500532 072155 | SYRACUSE | NY | HC | A 44 year old Male reported Seizure |
| 013218 | 018 | 29-Jun-02 | ADVANTAGE 55 | 01155600120 | CORPUS CHRISTI | TX | HC | Unknown Adult (18-64 years old) Female reported Bullae/Blister and Joint Pain |
| 013218 | 019 | 05-Jul-02 | ADVANTAGE (NON-SPECIFIC) | | SUNSET HILLS | MO | HC | A 48 year old Female reported Shortness of Breath, Coughing/Choking, Sneezing, Bronchospasm, Skin Tingling/Numbness, Defective Muscle Coordination |
| 013218 | 020 | 26-Jun-02 | ADVANTAGE 9 | 01155600116 | SAN RAMON | CA | HC | A 9 year old Male reported Hives/Welts |
| 013218 | 021 | 26-Jul-02 | ADVANTAGE 10 | 01155600117 | BECKLEY | WV | HC | A 25 year old Female reported Tremor |
| 013312 | 016 | 16-Aug-02 | ADVANTAGE (NON-SPECIFIC) | | WAYNESBORO | PA | HC | A 46 year old Male reported Hives/Welts, Itching |
| 013312 | 017 | 10-Aug-02 | ADVANTAGE (NON-SPECIFIC) | | HEAVNER | OK | HC | A 58 year old Male reported Tremor, Body Aches, Elevated Blood Sugar, Fever/hyperthermia, Rash, Itching, Weight loss |
| | | | | | | | | |
| 013312 | 018 | 22-Aug-02 | ADVANTAGE 20 | 01155600119 | PLACENTIA | CA | HC | A 58 year old Female reported Congestion, Difficulty Breathing, Throat Swelling |
| 013312 | 019 | 21-Aug-02 | ADVANTAGE 55 | 01155600120 | SYRACUSE | NY | HC | A 19 year old Female reported Irritation/Pain, Flushed Skin |
| 013312 | 020 | 28-Aug-02 | ADVANTAGE (NON-SPECIFIC) | | HAYWARD | CA | HC | Unknown Adult (18-64 years old) Male reported Hives/Welts, Rash |
| 013425 | 014 | 07-Sep-02 | ADVANTAGE (NON-SPECIFIC) | | CLAREMONT | CA | HC | Unknown Adult (18-64 years old) Female reported Swelling |
| 013425 | 015 | 14-Sep-02 | ADVANTAGE 20 | 01155600119 | MEDINA | OH | HC | A 46 year old Female reported Irregular Heartbeat |
| 013425 | 016 | 14-Sep-02 | ADVANTAGE 9 | 01155600116 | ORLANDO | FL | HC | A 24 year old Female reported Rash, Fever/Hyperthermia |
| 013425 | 017 | 25-Sep-02 | ADVANTAGE (NON-SPECIFIC) | | INDIANAPOLIS | IN | HC | A 26 year old Male reported Itching, Hives/Welts |
| 013425 | 018 | 01-Sep-02 | ADVANTAGE (NON-SPECIFIC) | | LOVILIA | IA | HC | A 20 year old Male reported Itching, Hives/Welts |
| 013425 | 019 | 25-Sep-02 | ADVANTAGE 9 | 01155600116 | SANDY CREEK | NY | HC | Unknown Adult (18-64 years old) Female reported Redness, Swelling, Watery Eyes, Irritation/Pain |
| 013425 | 020 | 01-Jan-01 | ADVANTAGE (NON-SPECIFIC) | | WINTERHAVEN | FL | HC | A 70 year old Female reported Allergic Reaction |
| 013543 | 001 | 15-Aug-02 | ADVANTAGE 10 | 01155600117 | RICHMOND | TX | HC | A 65 year old Male reported Rash, Hives/Welts, Fever/Hyperthermia, Nasal Discharge, Coughing/Choking |
| 013543 | 002 | 20-Oct-02 | ADVANTAGE 9 | 01155600116 | | GA | HC | Unknown Adult (18-64 years old) Female reported Hives/welts, Pruritus/Itching, Edema/Swelling |
| 013543 | 003 | 13-Oct-02 | ADVANTAGE 10 | 01155600117 | | PA | HC | A 53 year old Female reported Hives/Welts, Respiratory Irritation, Chest Pain, Irregular Heart Beat, Hypoglycemia |
| 013606 | 009 | 18-Nov-02 | PRE-EMPT PROFESSIONAL COCKROACH GEL BAIT | 00312500525 003225 | EAST ROCHESTER | NY | HC | 18 month old Baby Male reported Edema |
| 013606 | 010 | 19-Nov-02 | PREMISE (NON-SPECIFIC) | | FOUNTAIN HILLS | AZ | HC | A 54 year old Male reported Hives/Welts and Pruritus |
| 013625 | 001 | 04-Nov-02 | ADVANTAGE 20 | 01155600119 | TROY | AL | HC | A 45 year old Female reported Numbness in Right Index Finger and Elbow |
| 013625 | 002 | 03-Nov-02 | ADVANTAGE 9 | 01155600116 | FAYETTEVILLE | NY | HC | Unknown Adult (18-64 years old) Male reported Hives/Welts, Sinus Symptoms |
| 013625 | 003 | 07-Nov-02 | ADVANTAGE 55 | 01155600120 | MASONTOWN | PA | HC | Unknown Adult (18-64 years old) Female reported Nausea and Dizziness/Vertigo |
| 013674 | 001 | 03-Dec-02 | ADVANTAGE 18 | 01155600118 | TYLER | TX | HC | Unknown Adult (18-64 years old) Male reported Corneal Abrasion |

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| 013703 | 002 | 04-Sep-02 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | LEXINGTON | KY | HC | A 41 year old Male reported Headache, Nausea, Photophobia and Memory Loss |
| 013741 | 001 | 11-Jan-03 | ADVANTAGE 55 | 01155600120 | BELLINGHAM | MA | HC | Unknown Adult (18-64 years old) Female reported Muscle twitching in Face and Legs |
| 013741 | 002 | 19-Jan-03 | ADVANTAGE (NON-SPECIFIC) | | | WV | HC | A 17 year old Female reported Rash on Arms, Shoulders, Stomach and Chest |
| 013778 | 005 | 17-Jan-02 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | YAKIMA | WA | HC | A 37 year old Female reported Paralysis, Hair Loss, Dermal Irritation/Pain, Emotional Problems, Stress, Anorexia, Weight loss |
| 013814 | 001 | 17-Mar-03 | PREMISE 0.5 SC | 00312500497 | ARLINGTON | VA | HC | Unknown Adult (18-64 years old) Female reported Fast Heart Beat, Wheezing, Diarrhea, Coughing |
| 013844 | 001 | 05-Jan-03 | ADVANTAGE 100 | 01155600122 | | RI | HC | A 17 year old Female reported Hot Flashes, Erythema/Flushed, Dermal Irritation and Pain |
| 013844 | 002 | 03-Feb-03 | ADVANTAGE 18 | 01155600118 | OWEGO | NY | HC | A 38 year old Male reported Erythema/Flushed, Bullae/Blisters, Edema, Dermal Irritation/Pain |
| 013844 | 003 | 25-Feb-03 | ADVANTAGE 10 | 01155600117 | HOUSTON | TX | HC | Unknown Adult (18-64 years old) Female reported Rash on Face and Lower Legs |
| 013930 | 003 | 17-Feb-03 | MERIT 75 WP INSECTICIDE | 00312500421 | CHICAGO | IL | HC | A 19 year old Female reported Dehydration, Vomiting, Respiratory Irritation |
| 013943 | 001 | 21-Feb-03 | ADVANTAGE 100 | 01155600122 | WASHINGTON | DC | HC | Unknown Adult (18-64 years old) Female reported Blurred Vision, Ocular Irritation/Pain, Ulceration |
| 013943 | 003 | 13-Mar-03 | ADVANTAGE 9 | 01155600116 | | CA | HC | Unknown Adult (18-64 years old) Female reported Rash and Pruritus |
| 014005 | 002 | 04-Apr-03 | ADVANTAGE 100 | 01155600122 | REDDING | CA | HC | Unknown Adult (18-64 years old) Female reported Rash and Pruritus |
| 014005 | 003 | 04-Apr-03 | ADVANTAGE (NON-SPECIFIC) | | LAWRENCE | KS | HC | A 18 year old Female reported Hives/Welts |
| 014005 | 005 | 07-Apr-03 | ADVANTAGE 20 | 01155600119 | PICKERINGTON | OH | HC | A 22 year old Female reported Rash, Pruritus, Dermal Irritation/Pain, Fever/Hyperthermia, Chills, Throat Irritation |
| 014005 | 007 | 17-Apr-03 | ADVANTAGE 9 | 01155600116 | SAN FRANCISCO | CA | HC | Unknown Adult (18-64 years old) Female reported Abdominal Pain, Diarrhea, Fever/Hyperthermia |
| 014005 | 011 | 26-Apr-03 | ADVANTAGE 55 | 01155600120 | SARVER | PA | HC | A 13 year old Male reported Erythema/Flushed, Edema and Rash |
| 014029 | 002 | 17-Apr-03 | ADMIRE 2F FLOWABLE INSECTICIDE | 00312500422 | CONRAY | SC | HC | A 48 year old Female reported Dermal Irritation/Pain, Erythema/Flushed, Hives/Welts |
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| 014122 | 001 | 06-May-03 | ADVANTAGE (NON-SPECIFIC)LIQUID FORMULATION | | | NJ | HC | A 2 year old Male Child reported Hives/Welts |
| 014122 | 002 | 01-Jan-02 | ADVANTAGE (NON-SPECIFIC)LIQUID FORMULATION | | | CA | HC | A 46 year old Female reported Tingling sensation in Fingers, Tongue, Lips, Hot and cold flashes |
| 014122 | 003 | 06-May-03 | ADVANTAGE 100 | 01155600122 | | OH | HC | A 46 year old Male reported Edema, Erythema/Flushed, Dermal Irritation/Pain |
| 014122 | 008 | 22-May-03 | ADVANTAGE (NON-SPECIFIC)LIQUID FORMULATION | | MORGAN FIELD | KY | HC | Unknown youth (6-17 years old) Male reported Hives/Welts |
| 014122 | 009 | 07-May-03 | ADVANTAGE 100 (LIQUID FORMULATION) | 01155600122 | NORTH AGUSTA | SC | HC | A 43 year old Female reported Rash on Arms |
| 014114 | 001 | 01-Mar-03 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | LYNCHBURG | VA | HC | A 56 year old Male reported Leukoderma on Arms |
| 014114 | 017 | 05-May-03 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | EDWARDSVILLE | IL | HC | Unknown Adult (18-64 years old) Female reported Rash, Fever/Hyperthermia |
| 014114 | 023 | 11-May-03 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | | NH | HC | A 30 year old Male reported Dermal Irritation/Pain, Erythema/Flushed and Hives/Welts |
| 014201 | 003 | 03-May-03 | ADVANTAGE 10 | 01155600117 | TACOMA | WA | HC | A 46 year old Female reported Hives/Welts on Entire Body Area |

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| 014201 | 007 | 07-Jun-03 | ADVANTAGE 20 | 01155600119 | | CA | HC | Unknown Adult (18-64 years old) Female reported Swollen Eyes and Hives |
| 014201 | 008 | 05-Jun-03 | ADVANTAGE (NON-SPECIFIC) | | CLEVELAND | TN | HC | A 14 year old Female reported Pruritus/itching and Rash |
| 014201 | 012 | 14-Jun-03 | K9 ADVANTIX (NON-SPECIFIC) | | SAN ANTONIO | TX | HC | A 6 year old Female reported Hives/Welts |
| 014201 | 013 | 24-Jun-03 | ADVANTAGE (NON-SPECIFIC) | | YAHALA | FL | HC | A 39 year old Female reported Edema/Swelling |
| 014192 | 014 | 06-Jun-03 | SEASON-LONG CRUB CONTROL GRANULES | 00312500508 072155 | MIDLOTHIAN | VA | HC | A 42 year old Male reported Diarrhea, Abdominal Pain |
| 014286 | 002 | 05-Jul-03 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | FT WORTH | TX | HC | A 5 year old Male reported Edema and Open Sores |
| 014300 | 001 | 04-May-03 | ADMIRE 2F FLOWABLE INSECTICIDE | 00312500422 | | VA | HC | Unknown Adult (18-64 years old) Male reported Bleeding, Dermatitis, Small Ulcers, Dermal Irritation/Pain |
| 14286 | 013 | 03-May-03 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | MUSKEGON | MI | HC | A 61 year old Female reported Dermal Irritation/Pain |
| 014286 | 020 | 21-Jul-03 | SEASON-LONG CRUB CONTROL READY-TO-SPRAY | 00312500528 072155 | KANSAS CITY | MO | HC | Unknown Adult (18-64 years old) Male reported Edema |
| 014323 | 004 | 01-Jan-03 | ADVANTAGE (NON-SPECIFIC) | | CROMWELL | IN | HC | A 51 year old Female reported Hives/Welts, Pruritus |
| 014323 | 005 | 14-Jul-03 | ADVANTAGE 55 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600120 | NORTH CANTON | OH | HC | A 24 year old Male reported Hives/Welts |
| 014323 | 006 | 14-Jul-03 | ADVANTAGE 55 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600120 | NORTH CANTON | OH | HC | A 38 year old Female reported Hives/Welts |
| | | | SOLUTION | | | | | |
| 014422 | 001 | 25-Jul-03 | ADVANTAGE (NON-SPECIFIC) | | PITTSBURGH | PA | HC | A 2 year old Female Child reported Coughing/Choking, Wheezing, Pruritus, Hives/Welts |
| 014422 | 005 | 11-Aug-03 | ADVANTAGE 100 TOPICAL SOLUTION | 01155600122 | LAGUNA HILLS | CA | HC | A 47 year old Female reported Hives/Welts |
| 014422 | 008 | 21-Jul-03 | ADVANTAGE (NON-SPECIFIC) TOPICAL SOLUTION | | MALVERN | OH | HB | A 58 year old Female reported Coughing/Choking, Fever/Hyperthermia, Cytopenia, Malaise, Delusions, Liver Failure |
| 014422 | 009 | 22-Aug-03 | ADVANTAGE 100 TOPICAL SOLUTION | 01155600122 | VIRGINIA BEACH | VA | HC | A 19 year old Female reported Hives/Welts |
| 014422 | 010 | 27-Aug-03 | ADVANTAGE 55 TOPICAL SOLUTION | 01155600120 | HAVALOCK | NC | HC | Unknown Adult (18-64 years old) Female reported Redness, Ocular Irritation/Pain |
| 014427 | 012 | 26-Aug-03 | MARATHON 1% GRANULAR GREENHOUSE AND NURSERY INSECTICIDE | 00312500452 059807 | | TX | HC | A 29 year old Female reported Headache, Vomiting |
| 014459 | 001 | 01-Feb-03 | PREMISE GEL | 00312500544 | SEFNER | FL | HC | A 71 year old Male reported Shortness of Breath, Coughing/Choking, Dyspnea, Syncope |
| 014504 | 001 | 30-Aug-03 | ADVANTAGE 20 TOPICAL SOLUTION | 01155600119 | BUFFALO | NY | HC | A 58 year old Female reported Dermal Irritation/Pain |
| 014504 | 002 | 04-Jul-03 | ADVANTAGE 10 TOPICAL SOLUTION | 01155600117 | NEWPORT BEACH | CA | HC | A 63 year old Female reported Hives/Welts |
| 014504 | 004 | 28-Aug-03 | ADVANTAGE TOPICAL SOLUTION (NON-SPECIFIC) | | CHARLOTTE, GASTONIA | NC | HC | Unknown Adult (18-64 years old) Female reported Dermal Irritation/Pain, Bullae/Blisters, Erythema/Flushed, Pruritus |
| 014504 | 009 | 11-Sep-03 | ADVANTAGE 20 TOPICAL SOLUTION | 01155600119 | KINSLIN | OH | HC | A 25 year old Female reported Numbness |
| 014504 | 010 | 10-Sep-03 | ADVANTAGE 9 TOPICAL SOLUTION | 01155600116 | TIGARD | OR | HC | A 53 year old Female reported Dermal Irritation/Pain, Pruritus, Erythema/Flushed, Hives/Welts |
| 014504 | 011 | 16-Sep-03 | ADVANTAGE (NON-SPECIFIC) | | EL CAJON | CA | HC | A 87 year old Female reported Ocular Irritation/Pain, Redness, Drainage |
| 014504 | 013 | 20-Sep-03 | ADVANTAGE 55 TOPICAL SOLUTION | 01155600120 | HOLLOW ROCK | TN | HC | A 52 year old Male reported Hives/Welts, Pruritus |
| 014504 | 014 | 29-Sep-03 | ADVANTAGE 18 TOPICAL SOLUTION | 01155600118 | PHILADELPHIA | PA | HC | Unknown Adult (18-64 years old) Male reported Shortness of Breath, Fever/Hyperthermia, Headache, Nausea |
| 014616 | 002 | 03-Oct-03 | ADVANTAGE 20 | 01155600119 | JACKSONVILLE | FL | HC | A 36 year old Female reported Edema, Bullae/Blisters |
| 014616 | 004 | 04-Oct-03 | ADVANTAGE 9 | 01155600116 | POWDER SPRINGS | GA | HC | A 43 year old Female reported Hives/Welts, Respiratory Irritation |
| 014616 | 005 | 07-Oct-03 | ADVANTAGE 55 | 01155600120 | SALINAS | CA | HC | Unknown Adult (18-64 years old) Female reported Dermal |

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| | | | | | | | | Irritation/Pain, Red Spots in Mouth/Throat |
| 014616 | 006 | 10-Oct-03 | ADVANTAGE 20 | 01155600119 | CHILLICOTHE | OH | HC | A 14 year old Female reported Rash, Hives/Welts, Diarrhea |
| 014616 | 007 | 10-Oct-03 | ADVANTAGE 55 | 01155600120 | LEECHBURG | PA | HC | A 28 year old Female reported Erythema/Flushed, Rash, Hives/Welts |
| 014616 | 008 | 07-Oct-03 | ADVANTAGE 20 | 01155600119 | YOUNGSVILLE | PA | HC | A 14 year old Female reported Rash |
| 014616 | 009 | 21-Sep-03 | ADVANTAGE 100 | 01155600122 | PARMA | OH | HC | A 3 year old Female Child reported Bullae/Blister |
| 014616 | 010 | 17-Oct-03 | ADVANTAGE 55 | 01155600120 | GROVES | TX | HC | A 78 year old Female reported Rash, Erythema/Flushed, Edema, Pruritus |
| 014616 | 012 | 25-Oct-03 | ADVANTAGE 100 | 01155600122 | COVINGTON | WA | HC | A 70 year old Male reported Hives/Welts |
| 014616 | 013 | 27-Sep-03 | ADVANTAGE 9 | 01155600116 | CYPRUS | CA | HC | A 64 year old Female reported Chills, Nausea, Edema, Irregular Heartbeat |
| 014616 | 014 | 22-Oct-03 | ADVANTAGE 55 | 01155600120 | WEATHERFORD | TX | HC | A 46 year old Female reported Rash on Face, Neck, Arms and Torso |
| 014620 | 011 | 25-Oct-03 | MERIT (NON-SPECIFIC) | | AURORA | IL | HC | A 12 year old Female reported Rash on Entire Body Area |
| 014620 | 015 | 21-Oct-03 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | | ID | HC | Unknown Adult (18-64 years old) Male reported Chemical Burn on Hand |
| 014670 | 001 | 03-Nov-03 | ADVANTAGE 10 TOPICAL SOLUTION | 01155600117 | KANSAS CITY | MO | HC | A 49 year old Female reported Rash, Pruritus |
| 014670 | 002 | 07-Nov-03 | ADVANTAGE 20 TOPICAL SOLUTION | 01155600119 | | TX | HC | A 24 year old Female reported Rash, Fever/Hyperthermia |
| 014718 | 008 | 03-Dec-03 | MARATHON 1% GRANULAR GREENHOUSE AND NURSERY INSECTICIDE | 00312500452 059807 | | FL | HC | A 78 year old Male reported Headache, Visual Defect |
| 014765 | 001 | 19-Nov-03 | ADVANTAGE 18 | 01155600118 | PONTIAC | IL | HC | A 35 year old Female reported Hives/Welts |
| 014824 | 001 | 01-Oct-03 | ADVANTAGE 18 TOPICAL SOLUTION | 01155600118 | LAKE WORTH | FL | HC | Unknown Adult (18-64 years old) Female reported Dizziness/Vertigo, Nausea, Tinnitus, Muscle Weakness, Myalgia, Orthopnea, Loss Of Sense Of Taste |
| 014824 | 002 | 23-Jan-04 | ADVANTAGE 55 | 01155600120 | | CA | HC | A 56 year old Female reported Anxiety |
| 014923 | 002 | 01-Aug-03 | ADVANTAGE 55 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600120 | | LA | HC | A 62 year old Female reported Pruritus, Edema, Oral Irritation, Hypotension, Tachycardia |
| 014923 | 003 | 01-Jan-03 | ADVANTAGE TM 10 (IMIDACLOPRID) TOPICAL SOLUTION | 01155600117 | | TX | HC | Unknown Adult (18-64 years old) Female reported Rash |
| 014960 | 002 | 01-Jan-03 | ADVANTAGE 18 TOPICAL SOLUTION | 01155600118 | CRYSTIANNA | PA | HC | A 48 year old Female reported Hives/Welts |
| 014962 | 009 | 30-Mar-03 | PREMISE (NON-SPECIFIC) | | PHOENIX | AZ | HC | A 62 year old Female reported Throat Irritation |
| 014962 | 012 | 13-Mar-04 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | BEND | OR | HC | A 56 year old Male reported Rash, Erythema/Flushed, Edema |
| 015112 | 002 | 09-Apr-04 | ADVANTAGE 20 | 01155600119 | DELHI | CA | HC | Unknown Adult (18-64 years old) Female reported Rash, Pruritus |
| 015112 | 006 | 20-Apr-04 | ADVANTAGE 10 | 01155600117 | CRESTWELL | OR | HC | A 43 year old Female reported Hives/Welts |
| 015112 | 007 | 25-Apr-04 | ADVANTAGE 18 | 01155600118 | NASHVILLE | TN | HC | Unknown Adult (18-64 years old) Male reported Ocular Irritation/Pain, Redness |
| 015155 | 003 | 02-May-04 | ADVANTAGE 100 | 01155600122 | FALLON | NV | HC | Unknown Adult (18-64 years old) Female reported Dermal Irritation/Pain, Erythema/Flushed, Pruritus, Rash |
| 015155 | 005 | 06-May-04 | ADVANTAGE 100 | 01155600122 | POINT MUGU NAVAL AIR STA | CA | HC | Unknown Adult (18-64 years old) Male reported Rash, Edema |
| 015155 | 007 | 13-May-04 | ADVANTAGE 55 | 01155600120 | DELRAY BEACH | FL | HC | A 30 year old Female reported Rash on Hands, Arms, Back, Legs |
| 015155 | 008 | 20-May-04 | ADVANTAGE 55 | 01155600120 | NEW PORT RICHIE | FL | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Pruritus |
| 015178 | 009 | 29-Apr-04 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | | MN | HC | Unknown Adult (18-64 years old) Male reported Fever/Hyperthermia, Painful Kidneys |

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| 015178 | 018 | 22-May-04 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | NECEDAH | WI | HC | Unknown Adult (18-64 years old) Female reported Rash, Fever/Hyperthermia |
| 015244 | 004 | 04-Jun-04 | TREE & SHRUB INSECT CONTROL (1 GAL) | 00312500545 072156 | NAPA | ID | HC | Unknown Adult (18-64 years old) Male reported Diarrhea, Nausea |
| 015270 | 002 | 13-May-04 | ADVANTAGE (NON-SPECIFIC) | | EUGENE | OR | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 015270 | 003 | 20-May-04 | ADVANTAGE 20 | 01155600119 | BROOKVILLE | FL | HC | A 46 year old Female reported Hives/Welts |
| 015270 | 005 | 18-Jun-04 | ADVANTAGE 10 | 01155600117 | | CA | HC | A 35 year old Female reported Hives/Welts |
| 015270 | 006 | 18-Jun-04 | ADVANTAGE 10 | 01155600117 | TUSCOLSA | AL | HC | A 7 year old Female reported Rash on Face, Arms and Legs |
| 015270 | 008 | 22-Jun-04 | ADVANTAGE 100 | 01155600122 | SACRAMENTO | CA | HC | A 42 year old Female reported Tingling, Edema |
| 015374 | 001 | 03-Jul-04 | ADVANTAGE 9 TOPICAL SOLUTION | 01155600116 | LAKE ARIEL | PA | HC | A 6 year old Female reported Hives/Welts |
| 015374 | 002 | 02-Jul-04 | ADVANTAGE 18 | 01155600118 | FORT BRAGG | CA | HC | A 51 year old Female reported Dermal Irritation/Pain, Erythema/Flushed, Pruritus |
| 015374 | 005 | 16-Jun-04 | ADVANTAGE 100 | 01155600122 | TOLONO | IL | HC | A 54 year old Female reported Dermal Irritation/Pain, Pruritus |
| 015374 | 006 | 17-Jul-04 | ADVANTAGE 55 | 01155600120 | NASHVILLE | TN | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 015374 | 007 | 16-Jul-04 | ADVANTAGE 55 | 01155600120 | BATON ROUGE | LA | HC | Unknown Adult (18-64 years old) Male reported Bullae/blisters, Rash |
| 015374 | 008 | 12-Jul-04 | ADVANTAGE 20 | 01155600119 | ELK PARK | NC | HC | Unknown Adult (18-65) Male reported Fever/hyperthermia, Ataxia |
| 015418 | 003 | 05-Jul-04 | MERIT 0.5 G INSECTICIDE | 00312500451 | | CA | HC | Unknown Adult (18-64 years old) Male reported Fever/Hyperthermia, Nausea |
| 015418 | 005 | 06-Jul-04 | PREMISE 2 INSECTICIDE | 00312500454 | | CA | HC | Unknown Adult (18-64 years old) Female reported Abnormal Mentation, Throat Irritation, Oral Irritation |
| 015418 | 013 | 27-Jul-04 | MERIT 75 WP INSECTICIDE | 00312500421 | | CA | HC | A 33 year old Male reported Rash on Back |
| 015418 | 016 | 31-Jul-04 | MERIT 0.5 G INSECTICIDE | 00312500451 | BOSIE | ID | HC | A 53 year old Male reported Dizziness/Vertigo, Slurred Speech/Loss of Vision |
| 015418 | 025 | 15-May-04 | TREE SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | BENISIA | CA | HC | A 65 year old Female reported Diarrhea, Nausea, Concentrated Urine |
| 015418 | 026 | 14-Jul-04 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | AUSTIN | TX | HC | Unknown Adult (18-64 year old) Male reported Vomiting, Nausea, Muscle Cramps |
| 015418 | 027 | 15-Jul-04 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | PHILADELPHIA | PA | HC | Unknown Adult (18-64 years old) Male reported Myalgia |
| 015466 | 007 | 29-Aug-04 | ADVANTAGE 20 | 01155600119 | CYPRUS | CA | HC | Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain, Burns on Eyes |
| 015466 | 008 | 31-Aug-04 | ADVANTAGE 10 | 01155600117 | CONROE | TX | HC | Unknown Adult (18-64 years old) Female reported Malaise, Swollen Lymph Nodes, Increase Blood Pressure |
| 015466 | 009 | 28-Aug-04 | ADVANTAGE 55 | 01155600120 | HOUSTON | TX | HC | A 27 year old Male reported Hives/Welts |
| 015473 | 011 | 29-Feb-04 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | NORFOLK | VA | HC | Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain, Congestion, Dyspnea, Nasal Irritation |
| 015473 | 013 | 26-Jul-04 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | NAMPA | ID | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 015475 | 001 | 25-Aug-04 | PREMISE | 00043201332 | NORFOLK | VA | HC | Unknown Adult (18-65 years old) Husband & Wife reported Burning Eyes, Nose, Throat, Chest |
| 015589 | 001 | 10-Sep-04 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | | TN | HC | Unknown Adult (18-64 years old) Male reported Nausea, Dizziness/Vertigo |
| 015606 | 001 | 04-Jul-04 | ADVANTAGE 100 | 01155600122 | MARSHALL | MI | HC | Unknown Adult (18-64 years old) Female reported Cytopenia, Drowsiness/Lethargy |
| 015606 | 003 | 18-Sep-04 | ADVANTAGE 18 | 01155600118 | FEDERAL WAY | WA | HC | A 49 year old Female reported Lacrimation, Ocular Irritation/Pain, Yellow Colored Discharge |

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| 015606 | 004 | 23-Sep-04 | ADVANTAGE 18 | 01155600118 | | CA | HC | A 78 year old Male reported Fever/Hyperthermia, Tremor |
| 015662 | 002 | 14-Oct-04 | ADVANTAGE 18 | 01155600118 | POTASKOLA | OH | HC | Unknown Adult (18-64 years old) Female reported Rash to Face, Stomach, Arms, Legs, Chest and Back |
| 015662 | 005 | 11-Oct-04 | ADVANTAGE (NON-SPECIFIC) | | KENNEBUNKPORT | ME | HC | A 28 year old Female reported Edema, Pruritus, Hives/Welts |
| 015662 | 006 | 26-Oct-04 | ADVANTAGE 9 | 01155600116 | GARNER | NC | HC | Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain |
| 015662 | 008 | 25-Oct-04 | ADVANTAGE 10 | 01155600117 | | TX | HC | A 4 year old Male child reported Rash on Entire Body Area |
| 015662 | 009 | 16-Oct-04 | ADVANTAGE 100 | 01155600122 | WELLFLEET | MA | HC | Unknown Adult (18-64 years old) Female reported Dermal Irritation/Pain, Pruritus |
| 015687 | 002 | 11-Oct-04 | MERIT (NON SPECIFIC) | | KEYS | FL | HC | A 49 year old Male reported Dermal Irritation/Pain |
| 015687 | 010 | 17-Oct-04 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | NORMAN | OK | HC | A 37 year old Female reported Rash on Entire Body Area, Swollen Tongue |
| 015777 | 001 | 18-Oct-04 | ADVANTAGE 9 | 01155600116 | BRIGANTINE | NJ | HC | A 76 year old Female reported Pruritus, Hives/Welts |
| 015777 | 002 | 13-Oct-04 | ADVANTAGE 18 | 01155600118 | SHAVERTOWN | PA | HC | Unknown Adult (18-64 years old) Female reported Pruritus |
| 015777 | 003 | 02-Nov-04 | ADVANTAGE 100 | 01155600122 | MALAPAN | FL | HC | A 44 year old Female reported Edema, Dyspnea |
| 015777 | 004 | 06-Nov-04 | ADVANTAGE 18 | 01155600118 | SAN DIEGO | CA | HC | A 30 year old Female reported Nausea, Dizziness/Vertigo |
| 015777 | 005 | 05-Nov-04 | ADVANTAGE 20 | 01155600119 | WALNUT CREEK | CA | HC | Unknown Adult (18-64) Female reported Hives/Welts, Pruritus |
| 015777 | 007 | 23-Nov-04 | ADVANTAGE 18 | 01155600118 | TAMPA | FL | HC | Unknown Adult (18-64 years old) Female reported Palpitations, Hypotension, Diaphoresis, Vomiting, Shaky Hands, Rash |
| 015834 | 001 | 01-Jan-02 | K9 ADVANTIX (NON-SPECIFIC) | | | LA | HC | A 51 year old Male reported Rash |
| 015834 | 002 | 08-Oct-04 | ADVANTAGE 9 | 01155600116 | BEARDSTOWN | IL | HC | A 58 year old Female reported Rash |
| 015834 | 003 | 22-Nov-04 | ADVANTAGE 9 | 01155600116 | MUNCY | PA | HC | A 65 year old Female reported Rash |
| 015834 | 006 | 12-Dec-04 | ADVANTAGE 55 | 01155600120 | AUBURN | WA | HC | A 30 year old Female reported Rash |
| 015834 | 007 | 12-Dec-04 | ADVANTAGE 55 | 01155600120 | AUBURN | WA | HC | A 7 year old Male reported Rash |
| 015834 | 008 | 12-Dec-04 | ADVANTAGE 55 | 01155600120 | AUBURN | WA | HC | A 13 year old Male reported Rash |
| 015864 | 005 | 28-Dec-03 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | POTOMAX | MD | HC | A 22 year old Male reported Renal Failure |
| 015864 | 008 | 07-Sep-04 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | LOVELAND | OH | HC | A 36 year old Male reported Dermal Irritation/Pain, Tingling Sensation in Legs |
| 015933 | 001 | 01-Jan-03 | K9 ADVANTIX (NON-SPECIFIC) | | JEFFERSON YORK | PA | HC | A 81 year old Male reported Dermal Rash |
| 015933 | 002 | 01-Jan-04 | ADVANTAGE 55 | 01155600120 | CHARLOTTE | NC | HC | Unknown Adult (18-64 years old) Female reported Dermal Rash |
| 015933 | 003 | 16-Jan-05 | ADVANTAGE 100 | 01155600122 | NEW PORT RICHEY | FL | HC | A 34 year old Male reported Joint Stiffness/Loss of Motion |
| 015933 | 004 | 26-Jan-05 | ADVANTAGE 55 | 01155600120 | LILLINGTON | NC | HC | A 78 year old Male reported Ocular Irritation/Pain, Red Eye/Conjunctivitis |
| 015975 | 001 | 31-Dec-04 | MARATHON 60 WP GREENHOUSE AND NURSERY INSECTICIDE IN WSP | 00312500492 059807 | JOLIET | IL | HC | A 45 year old Female reported Nausea, Paresthesia, Erythema/Flushed |
| 015975 | 008 | 26-Jan-05 | PREMISE FOAM | 00043201391 | STANFORD | FL | HC | Unknown Adult (18-64 years old) Male reported Dermal Irritation/Pain, Edema |
| 016011 | 006 | 15-Feb-05 | PREMISE (NON-SPECIFIC) | | | FL | HC | Unknown Adult (18-64 years old) Male reported Headache, Upset Stomach |
| 016106 | 001 | 31-Aug-04 | ADVANTAGE (NON-SPECIFIC) | | BOULDER CREEK | CA | HC | A 41 year old Male reported Hypothermia, Confusion, Drowsiness/Lethargy, Headache |
| 016106 | 003 | 01-Jan-05 | ADVANTAGE 9 | 01155600116 | FISHERSVILLE | VA | HC | Unknown Adult (18-64 years old) Male reported Coughing/choking |
| 016169 | 001 | 01-Jan-05 | MARATHON II | 00043201369 059807 | | IN | HC | Unknown Adult (18-64 years old) Male reported Malaise and Weight Loss |
| 016214 | 001 | 01-Apr-05 | ADVANTAGE 100 | 01155600122 | FLAT ROCK | NC | HC | A 13 year old Male reported Rash |

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| 016214 | 002 | 01-Jan-05 | ADVANTAGE (NON-SPECIFIC) | | MOREHEAD CITY | NC | HC | A Male Child reported Renal Failure |
| 016214 | 003 | 01-Jan-05 | ADVANTAGE 20 | 01155600119 | KILAMONT | OR | HC | Unknown Adult (81-64 years old) Male reported Hives/Welts, Pruritus |
| 016247 | 015 | 19-Apr-05 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | NASHVILLE | IL | HC | A 49 year old Male reported Rash, Pruritus |
| 016292 | 003 | 10-Apr-05 | ADVANTAGE 9 | 01155600116 | POMPAHO | FL | HC | A 28 year old Male reported Hives/Welts |
| 016328 | 011 | 25-Mar-05 | 3-IN-1 ROSE & FLOWER POTTING MIX (10 QT) | 00312500532 072155 | ATLANTA | GA | HC | A 57 year old Female reported Dermal Irritation/Pain |
| 016328 | 012 | 01-Jan-03 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | OAKLYN | NJ | HC | A 46 year old Male reported Diaphragm Sensitivity, Elevated Blood Levels |
| 016328 | 019 | 09-Apr-05 | MERIT 2 INSECTICIDE | 00312500418 | COLUMBUS | OH | HC | A 55 year old Male reported Edema, Joint Pain, Swelling and Aching |
| 016328 | 022 | 01-Apr-05 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | PHOENIX | AR | HC | A 20 year old Male reported Facial Tremors |
| 016352 | 241 | 11-May-05 | GRUBEX | 00043201339 000538 | NEW AUBURN | WI | HC | Unknown Adult (18-64 years old) Female reported Stomach Cramps, Diarrhea |
| 016406 | 002 | 20-Jun-04 | ADVANTAGE (NON-SPECIFIC) | | AUSTIN | TX | HC | Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain, Corneal Abrasion |
| 016407 | 010 | 14-Jun-05 | TRIMAX INSECTICIDE | 00026400783 | KENNETT | MO | HC | A 58 year old Male reported Ocular Irritation/Pain, Blisters |
| 016396 | 563 | 22-Jun-05 | GRUBEX | 00043201339 000538 | POINT PLEASANT BEACH | NJ | HC | Unknown Adult (18-64 years old) Male reported Headache, Nausea, High Blood Pressure |
| 016595 | 007 | 07-Jul-05 | MARATHON 1% GRANULAR GREENHOUSE AND NURSERY INSECTICIDE | 00312500452 059807 | DURHAM | NC | HC | Unknown Adult (18-64 years old) Male reported Pruritus, Rash |
| 016595 | 023 | 24-Jul-05 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | COLUMBIA | MD | HC | A 54 year old Female reported Nausea, Dermal Irritation/Pain, Dizziness/Vertigo |
| 016595 | 024 | 01-Apr-05 | BAYER ADVANCED GARDEN ALL-IN-ONE POTTING MIX FOR ROSES & FLOWERS | 07215500010 | FOLSOM | CA | HC | Unknown Adult (18-64 years old) Male reported Pain, Headache, Body Aches |
| 016575 | 001 | 09-Jul-05 | ADVANTAGE 10 | 01155600117 | YUBA | CA | HC | A 23 year old Female reported Rash on Abdomen and Legs |
| 016575 | 002 | 09-Jul-05 | ADVANTAGE (NON-SPECIFIC) | | BATAVIA | NY | HC | Unknown Adult (18-64 years old) Female reported Erythema/Flushed, Pruritus, Rash, Dyspnea |
| 016575 | 004 | 16-Jul-05 | ADVANTAGE (NON-SPECIFIC) | | SAN FRANCISCO | CA | HC | Unknown Adult (18-64 years old) Female reported Erythema/Flushed, Hives/Welts, Pruritus, Rash |
| 016575 | 005 | 27-May-05 | ADVANTAGE (NON-SPECIFIC) | | FLINTVILLE | TN | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Pruritus |
| 016629 | 001 | 18-Aug-05 | ADVANTAGE 100 | 01155600122 | MERCER ISLAND | WA | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 016629 | 002 | 01-May-05 | ADVANTAGE 9 | 01155600116 | CLEVELAND | OH | HC | A 77 year old Female reported Rash on Back and and Near Chest |
| 016662 | 004 | 10-Aug-05 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | | MI | HC | A 67 year old Male reported Hives/Welts, Edema |
| 016662 | 011 | 01-Jul-05 | MERIT 75 WP INSECTICIDE | 00312500421 | RIVERSIDE | CA | HB | A 56 year old Female reported Respiratory Irritation, Coughing Up Blood, Cardiac Arrest, Blood Clots in Legs |
| 016662 | 012 | 01-Jul-05 | MERIT 75 WP INSECTICIDE | 00312500421 | RIVERSIDE | CA | HC | A 68 year old Male reported Rash |
| 016662 | 016 | 01-Jan-05 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | SENATOBIA | MS | HB | A 20 year old Male reported Fever/Hyperthermia, Dyspnea |
| 016662 | 017 | 22-Aug-05 | MERIT (NON-SPECIFIC) | | | CO | HC | Unknown Adult (18-64 years old) Female reported Nausea, Congestion, Respiratory Irritation, Dyspnea, Headache |
| 016652 | 065 | 27-Aug-05 | SCOTTS GRUBEX | 00312500463 000538 | LOCKPORT | NY | HC | A 61 year old Male reported Dizziness/Vertigo |
| 016732 | 006 | 22-Sep-05 | ADVANTAGE (NON-SPECIFIC) | | OXNARD | CA | HC | A 3 year old Male Child reported Rash on Arms, Face, Neck, Abdomen, Back of Legs |
| 016732 | 008 | 02-Aug-05 | ADVANTAGE 9 | 01155600116 | SILVEN BEACH | NY | HC | A 54 year old Female reported Rash on Arms |
| 016737 | 015 | 08-Sep-05 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | CASCADE | MD | HC | Unknown Adult (18-64 years old) Male reported Dermal Irritation/Pain, Erythema/Flushed |

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| 016737 | 018 | 26-Sep-05 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | FULTON | MO | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts, Pruritus |
| 016852 | 003 | 20-Oct-05 | ADVANTAGE (NON-SPECIFIC) | | SACRAMENTO | CA | HC | A 21 year old Female reported Rash |
| 016912 | 004 | 15-Oct-05 | SEASON-LONG GRUB CONTROL GRANULES | 00312500508 072155 | | MO | HC | Unknown Adult (18-64 years old) Female reported Abdominal Pain, Nausea, Bloody Diarrhea |
| 016912 | 005 | 17-Sep-05 | TREE & SHRUB INSEC CONTROL (32 OZ) | 00312500545 072155 | MORGAN | UT | HC | A 71 year old Female reported Diarrhea, Headache, Confusion |
| 017134 | 001 | 12-Dec-05 | ADVANTAGE 18 | 01155600118 | KIRKLAND | WA | HC | A 51 year old Female reported Rash |
| 017285 | 006 | 23-Jan-06 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | | TX | HB | Unknown Age Male Child reported Seizure, Headache, Encephalitis |
| 017349 | 001 | 17-Apr-06 | ADVANTAGE | | ETOWAH | TN | HC | A 68 year old Feale reported Hives/ Welts, Rash, Throat Irritation, Ear Discharge |
| 017349 | 002 | 10-Apr-06 | ADVANTAGE 55 | 01155600120 | PHILADELPHIA | PA | HC | A 45 year old Female reported Diarrhea |
| 017349 | 003 | 30-Apr-06 | ADVANTAGE | | CYPRESS | CA | HC | A 45 year old Female reported Ataxia, Confusion, Slurred Speech |
| 017358 | 001 | 02-Apr-06 | ADVANCED LAWN SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | | NY | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 017358 | 007 | 18-Apr-06 | ADVANCED LAWN SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | FAIR HOPE | AL | HC | A 63 year old Female reported Hives/Welts |
| 017358 | 011 | 25-Apr-06 | BAYER ADVANCED GRUB KILLER PLUS | 07215500044 | | PA | HC | Unknown Adult (18-64 years old) Female reported Joint Pain, Joint Swelling, Numbness/Pain on Hands and Arms |
| 017471 | 005 | 18-May-06 | ADVANTAGE 100 | 01155600122 | SAN JOSE | CA | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 017496 | 001 | 10-Apr-06 | SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | ROSEVILLE | CA | HC | Unknown Adult (18-64 years old) Female reported Rash |
| 017496 | 015 | 01-Jan-06 | TRIMAX PRO INSECTICIDE | 00026400855 | CINCINNATI | OH | HC | A 58 year old Male reported Lacrimation, Respiratory Irritation, Coughing/Choking, Ocular Irritation/Pain |
| 017496 | 022 | 01-May-06 | MALATHION 1% GRANULAR GREENHOUSE AND NURSERY INSECTICIDE | 00312500452 059807 | | MI | HC | Unknown Adult (18-64 years old) Female reported Syncope (Fainting Episode) |
| 017540 | 001 | 26-May-06 | ADVANTAGE 18 | 01155600118 | LOS ANGELES | CA | HC | Unknown Adult (18-64 years old) Female reported Rash on Stomach and Arms |
| 017540 | 002 | 01-Jun-06 | ADVANTAGE (NON-SPECIFIC) | | MADISON HEIGHTS | MI | HB | A 48 year old Female reptred Renal Failure |
| 017571 | 006 | 17-Jun-06 | SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | UPPER MAKEFIELD | PA | HC | Unknown Adult (18-64 years old) Male reported Erythema/Flushed, |
| | | | | | | | | Hives/Welts, Bee Sting |
| 017571 | 021 | 07-Jun-06 | MERIT (NON-SPECIFIC) | | | MD | HC | Unknown Adult (18-64 years old) Male reported Ocular Irritation/Pain, Eye Discharge |
| 017690 | 001 | 01-Jul-06 | ADVANTAGE 20 | 01155600119 | ROSEVILLE | CA | HC | Unknown Adult (18-64 years old) Female reported Rash |
| 017690 | 002 | 15-Jul-06 | ADVANTAGE 20 | 01155600119 | ANDERSON | CA | HC | A 60 year old Female reported Ocular Irritation/Pain, Burning Eye |
| 017690 | 003 | 17-Jul-06 | ADVANTAGE (NON-SPECIFIC) | | WILMINGTON | DE | HC | A 50 year old Female reported Rash, Pruritus |
| 017690 | 005 | 25-Jul-06 | ADVANTAGE 18 | 01155600118 | HOLLYWOOD | CA | HC | A 46 year old Male reported Ocular Irritation/Pain, Swollen Right Eye |
| 017690 | 006 | 27-Jul-06 | ADVANTAGE 9 | 01155600116 | MANTUAH | OH | HC | A 5 year old Female reported Hives/Welts |
| 017690 | 007 | 06-Jul-06 | ADVANTAGE 18 | 01155600118 | BEL AIR | MD | HC | A 11 year old Female reported Hives/Welts |
| 017691 | 004 | 01-Jul-06 | TREE & SHRUB INSECT CONTROL (32 OZ) | 00312500545 072155 | DALLAS | TX | HC | A 56 year old Female reported Pruritus, Hair Loss, Dermal Irritation/Pain, Bullae/Blisters |
| 017691 | 009 | 02-Jul-06 | MERIT (NON-SPECIFIC) | | BLOOMFIELD | NJ | HC | A 81 year old Male reported Hives/Welts |
| 017747 | 290 | 13-Jul-06 | GRUBEX | 00043201339 000538 | TROY | MI | HC | Unknown Adult (18-64 years old) Female reported Pain in Lower Right Rib Cage, Difficulty Breathing |

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| 017853 | 001 | 03-Aug-06 | ADVANTAGE (NON-SPECIFIC) | | DAYTONA BEACH | FL | HC | A 20 year old Female reported Ocular Lacrimation, Dyspnea, Shortness of Breath, Hives/Welts |
| 017853 | 002 | 03-Aug-06 | ADVANTAGE (NON-SPECIFIC) | | BERKELEY | CA | HC | A 59 year old Female reported Ocular Irritation/Pain, Eye Discharge, Redness/Conjunctivitis |
| 017853 | 004 | 04-Aug-06 | ADVANTAGE 20 | 01155600119 | ST. PETERSBURG | FL | HC | Unknown Adult (18-64 years old) Female reported Ocular Lacrimation, Irritation/Pain, Conjunctivitis |
| 017917 | 002 | 07-Sep-06 | ADVANTAGE 55 | 01155600120 | CITRUS HEIGHTS | CA | HC | Unknown Adult (18-64 years old) Female reported Hives/Welts |
| 017917 | 003 | 28-Jul-06 | ADVANTAGE (NON-SPECIFIC) | | JAMESTOWN | NY | HC | A 18 months Female Child reported Rash around Eyes |
| 018036 | 001 | 16-Oct-06 | ADVANTAGE 100 | 01155600122 | SPARTANBERG | SC | HC | A 39 year old Male reported Hives/Welts, Pruritus, Edema |
| 018036 | 004 | 29-Oct-06 | ADVANTAGE 18 | 01155600118 | BEL AIR | MD | HC | A 61 year old Male reported Taste Alteration |
| 018037 | 001 | 21-Sep-06 | MERIT 0.5 G | 00043201328 | NEWTON | CT | HC | Unknown Adult (18-64 years old) Male reported Hives/Welts |
| 018037 | 010 | 01-Apr-04 | PREMISE 75 WSP | 00043201332 | CRAWFORDVILLE | FL | HC | Unknown Adult (18-64 years old) Male reported Rash on Lower Legs and Head |
| 018142 | 001 | 02-Nov-05 | ADVANTAGE 18 | 01155600118 | SAN FRANCISCO | CA | HC | Unknown Adult (18-64 years old) Female reported Erythema/Flushed, Pruritus |
| 018179 | 001 | 14-Dec-06 | ADVANTAGE 18 | 01155600118 | LISBON | ME | HC | A 56 year old Male reported Erythema/Flushed, Pruritus, Hives/Welts |
| 018294 | 002 | 06-Jan-07 | ADVANTAGE 20 | 01155600119 | SANTA ROASA | CA | HC | A 54 year old Female reported Ocular Irritation/Pain, Redness/Conjunctivitis |
| 018294 | 004 | 21-Jan-07 | ADVANTAGE 100 | 01155600122 | EVANSVILLE | IN | HC | A 32 year old Male reported Corneal Abrasion, Ocular Irritation/Pain, Redness/Conjunctivitis |
| 018337 | 001 | 01-Jan-07 | ADVANTAGE 20 | 01155600119 | ALICE | TX | HC | Unknown Adult (18-64 years old) Female reported Rash on Legs and Arms |
| 018411 | 001 | 26-Jan-07 | ADVANTAGE (NON-SPECIFIC) | | TRINITY | TX | HC | Unknown Adult (18-64 years old) Female reported Dermal Irritation/Pain, Tingling |
| 018413 | 004 | 29-Mar-07 | SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | FORT MYERS | FL | HC | A 44 year old Female reported Pruritus, Headache, Photophobia |
| 018502 | 007 | 30-Mar-07 | PREMISE 75 INSECTICIDE IN WATER SOLUBLE PACKETS | 00312500455 | CHESAPEAKE | VA | HC | Unknown Adult (18-64 years old) Female reported Rash, Nausea, Dyspnea/Shortness of Breath |
| 018530 | 002 | 10-Apr-07 | ADVANTAGE 100 | 01155600122 | | CA | HC | Unknown Adult (18-64 years old) Female reported Corneal Abrasion, Ocular Irritation/Pain |
| 018530 | 004 | 27-Apr-07 | ADVANTAGE 18 | 01155600118 | MIAMI BEACH | FL | HC | A 40 year old Male reported Ocular Irritation/Pain |
| 018554 | 003 | 15-Feb-07 | ADVANTAGE 55 | 01155600120 | KYE COUNTY BEACH | FL | HC | A 70 year old Male reported Hives/Welts |
| 018599 | 022 | 08-May-07 | GRUBEX SEASON-LONG GRUB CONTROL 2 | 00043201339 000538 | PROVIDENCE | RI | HC | Unknown Adult (18-64 years old) Male reported Dizziness and Throat Irritation |
| 018599 | 060 | 25-May-07 | GRUBEX SEASON-LONG GRUB CONTROL | 00043201339 000538 | VIRGINIA BEACH | VA | HC | A 56 year old Male reported Diarrhea, Lethargy, Anorexia |
| 018599 | 061 | 29-May-07 | GRUBEX SEASON-LONG GRUB CONTROL 2 | 00043201339 000538 | WEYMOUTH | MA | HC | Unknown Adult (18-64 years old) Male reported Erythema, Color Alteration, Rash |
| 018642 | 003 | 07-Jun-07 | ADVANTAGE 55 | 01155600120 | CORNWALL | PA | HC | A 68 year old Female reported Ocular Irritation/Pain, Edema, Corneal Defect |
| 018732 | 040 | 10-Jun-07 | GRUBEX SEASON-LONG GRUB CONTROL | 00043201339 000538 | | MN | HC | A 15 month old Female Child reported Bullae/Blisters |
| 018732 | 083 | 27-Apr-07 | GRUBEX SEASON-LONG GRUB CONTROL 2 | 00043201339 000538 | MT GILEAD | OH | HC | A 71 year old Female reported Swollen Neck and Dyspnea |
| 018751 | 001 | 25-Jun-07 | ADVANTAGE 55 | 01155600120 | TULSA | OK | HC | A 48 year old Female reported Throat Irritation, Dyspnea, Coughing/Choking |
| 018764 | 004 | 30-May-07 | UNSPECIFIED ANT KILLING GRANULE | | COTTAGE GROVE | MN | HC | A 51 year old Female reported Vomiting, Nausea, Abdominal Pain, Bloating/Gas |
| 018764 | 010 | 02-Jul-07 | MERIT 75 WSP | 00043201318 | SHAMOKIN | PA | HC | A 37 year old Male reported Dizziness/Vertigo |
| 018764 | 014 | 02-Jul-07 | PREMISE 2 INSECTICIDE | 00312500454 | TEHACHAPI | CA | HC | Unknown Adult (18-64 years old) Female reported Rash on Entire Body Area |

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| 018893 | 003 | 04-Aug-07 | ADVANTAGE 20 | 01155600119 | NORTH MIAMI BEACH | FL | HC | A 53 year old Female reported Dermal Irritation/Pain, Edema |
| 018893 | 004 | 13-Aug-07 | ADVANTAGE (NON-SPECIFIC) | | AKRON | OH | HC | A 41 year old Female reported Hives/Welts |
| 018915 | 006 | 30-Jul-07 | GRUBEX SEASON-LONG GRUB CONTROL 3 | 00043201339 000538 | DES MOINES | IA | HC | A 49 year old Male reported Abdominal Pain, Edema, Pruritus, Rash, Diarrhea |
| 018940 | 016 | 01-Apr-07 | SEASON-LONG GRUB CONTROL GRANULES | 07215500044 | QUEENSBURY | NY | HC | A 62 year old Male reported Numbness in Toe |
| 018999 | 002 | 04-Sep-07 | ADVANTAGE 9 | 01155600116 | LARGO | FL | HC | A 49 year old Female reported Numbness, Respiratory Congestion |
| 018999 | 003 | 07-Sep-07 | ADVANTAGE 100 | 01155600122 | FERNANDINA BEACH | FL | HC | Unknown Adult (18-64 years old) Female reported Ocular Irritation/Pain |
| 018999 | 004 | 13-Sep-07 | ADVANTAGE 18 | 01155600118 | DOVER | NH | HC | A 37 year old Male reported Hives/Welts, Pruritus, Rash |
| 018999 | 006 | 10-Sep-07 | ADVANTAGE 10 | 01155600117 | LIVURNE | GA | HC | A 60 year old Female reported Hypertension, Tingling Sensation on Entire Left Side of Body |
| 019033 | 016 | 06-Sep-07 | 12-MONTH TREE & SHRUB INSECT CONTROL CONC. 32 OZ | 07215500055 | DENVER | CO | HC | Unknown Adult (18-64 years old) Male reported Tinnitus, Muscle Twitching |
| 019094 | 002 | 18-Aug-07 | ADVANTAGE 20 | 01155600119 | WEST MONROE | NY | HC | A 35 year old Male reported Hives/Welts |
| 019094 | 003 | 07-Oct-07 | ADVANTAGE 55 | 01155600120 | BELLEVIEW | FL | HC | A 3 year old Male Child reported Hives/Welts, Diarrhea |
| 019094 | 004 | 16-Oct-07 | ADVANTAGE (UNSPECIFIED) | | ROCKVILLE | MD | HC | A 53 year old Female reported Ataxia, Dizziness/Vertigo |
| 019094 | 005 | 14-Oct-07 | ADVANTAGE (UNSPECIFIED) | | TRINITY | TX | HC | A 80 year old Female reported Ocular Irritation/Pain, Blurred Vision, Redness/Conjunctivitis |
| 019094 | 007 | 13-Sep-07 | ADVANTAGE (UNSPECIFIED) | | GRANITE CITY | IL | HC | A 8 year old Female reported Hives/Welts, Erythema/Flushed, Pruritus, Rash |
| 019127 | 005 | 12-Oct-07 | PREMISE 2 INSECTICIDE | 00312500454 | ATLANTA | GA | HC | Unknown Adult (18-64 years old) Female reported Unspecified Gall Bladder Problem |
| 019127 | 015 | 01-Oct-07 | 12-MONTH TREE & SHRUB INSECT CONTROL CONC. 32 OZ | 07215500055 | EASTMAN | GA | HC | A 54 year old Female reported Rash, Pruritus |
| 019195 | 001 | 15-Sep-07 | ADVANTAGE 18 | 01155600118 | HINSDALE | MA | HC | A 51 year old Female reported Edema, Erythema, Pruritus, Dyspnea |
| 019299 | 001 | 01-Dec-07 | ADVANTAGE 100 | 01155600122 | OLIVEHURST | CA | HC | A 15 year old Female reported Erythema/Flushed, Pruritus, Rash |
| 019299 | 003 | 04-Dec-07 | ADVANTAGE 55 | 01155600120 | ALTAMONTE SPRINGS | FL | HC | Unknown Adult (18-64 years old) Male reported Edema |
| 019299 | 004 | 07-Dec-07 | ADVANTAGE 18 | 01155600118 | YORK | PA | HC | A 45 year old Female reported Rash around Mouth and Fingers |
| 019299 | 005 | 26-Dec-07 | ADVANTAGE 55 | 01155600120 | WESTERLO | NY | HC | A 41 year old Female reported Hives/Welts |
| 019310 | 002 | 22-Dec-07 | PREMISE (UNSPECIFIED) | | | | HC | Unknown Adult (18-64 years old) Female reported Vomiting and Severe Headache |
| 019348 | 001 | 20-Dec-07 | ADVANTAGE (UNSPECIFIED) | | JACKSONVILLE | FL | HC | A 43 year old Female reported Hives/Welts, Rash |
| 019444 | 001 | 20-Feb-08 | ADVANTAGE (NON-SPECIFIC) | | BLOOMSBURG | PA | HB | Unknown Adult (18-64 years old) Female reported Dermal Irritation/Pain, Erythema/Flushed, Dyspnea |
| 019444 | 002 | 15-Feb-08 | ADVANTAGE 100 | 01155600122 | RICHMOND | CA | HC | A 21 year old Female reported Ocular Irritation/Pain, Redness/Conjunctivitis |
| 019518 | 001 | 25-Feb-08 | ADVANTAGE 55 | 01155600120 | PONTIAC | MI | HC | Unknown Adult (18-64 years old) Male reported Dermal Irritation/Pain, Rash |
| 019518 | 002 | 20-Mar-08 | ADVANTAGE 20 | 01155600119 | JUDSONIA | AR | HC | A 52 year old Male reported Dermal Irritation/Pain, Erythema/Flushed, Pruritus, Rash, Hives/Welts |
| 019606 | 002 | 18-Apr-08 | ADVANTAGE (NON-SPECIFIC) | | EUGENE | OR | HC | A 64 year old Female reported Anaphylactic Reaction |
| 019647 | 003 | 01-Dec-07 | PREMISE (NON-SPECIFIC) | | THOMASVILLE | NC | HC | A 39 year old Female reported Dizziness/Vertigo, Nausea, Arthralgia |
| 019681 | 179 | 22-Apr-08 | GRUBEX SEASON-LONG GRUB CONTROL | 00043201339 000538 | SHANAHAN | IL | HC | A 4 year old Female Child reported Bumps on Arms, Legs and Top of Feet |

APPENDIX F. Glossary

APPENDIX

Organizations

| | |
|----------|--|
| CEPA-DPR | California Environmental Protection Agency, Department of Pesticide Regulation |
| EFED | Environmental Fate Effects Division |
| EFSA | European Food Safety Authority |
| EPA | U.S. Environmental Protection Agency |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| HED | Health Effects Division |
| OPP | Office of Pesticide Programs |
| OPPTS | Office of Prevention, Pesticides, and Toxic Substances |
| USDA | United States Department of Agriculture |
| WDOE | Washington Department of Ecology |
| WGHOGA | Willapa-Grays Harbor Oyster Growers Association |
| FESTF | FIFRA Endangered Species Task Force |
| IMS | Information Management System |
| FWS | U.S. Fish and Wildlife Service |
| DPS | Distinct Population Segment |
| NMFS | National Marine Fisheries Service |

Terms

| | |
|------------------|--|
| ACh | Acetylcholine |
| A.I. | Active Ingredient |
| aPAD | Acute Population Adjusted Dose |
| aRfD | Acute Reference Dose |
| ATV | All-Terrain Vehicle |
| AW | Focal Species Weight |
| BW | Body Weight |
| CFR | Code of Federal Regulations |
| cPAD | Chronic Population Adjusted Dose |
| cRfD | Chronic Reference Dose |
| DEEM-FCID | Dietary Exposure Evaluation Model-Food Commodity Intake Database |
| EDRT | Endocrine Disruptor Review Team |
| EDSP | Endocrine Disruptor Screening Program |
| EEC | Estimated Environmental Concentration |
| EUP | Experimental Use Permit |
| FIRST | FQPA Index Reservoir Screening Tool |
| FQPA | Food Quality Protection Act |
| GHS | Globally Harmonized System |
| GLP | Good Laboratory Practices |
| IDS | Incident Data System |
| IMI | Imidacloprid |
| K _d | Distribution Coefficient |
| K _{oc} | Soil Organic Carbon-Water Partition Coefficient |
| K _{ow} | Octanol-Water Partition Coefficient |
| LC ₅₀ | Median Lethal Concentration |
| LD ₅₀ | Median Lethal Dose |
| LOAEC | Lowest Observed Adverse Effects Concentration |

| | |
|-------|---|
| LOAEL | Lowest Observed Adverse Effects Level |
| LOC | Level of Concern |
| LOEC | Lowest Observed Effects Concentration |
| LOEL | Lowest Observed Effects Level |
| MMAD | Mass Median Aerodynamic Diameter |
| MOE | Margin of Exposure |
| nAChR | Nicotinic Acetylcholine Receptor |
| NOAEC | No Observed Adverse Effects Concentration |
| NOAEL | No Observed Adverse Effects Level |
| NOEC | No Observed Effects Concentration |
| NOEL | No Observed Effects Level |
| PAD | Population Adjusted Dose |
| PCE | Primary Constituent Element |
| PPB | Parts per Billion |
| PPM | Parts per Million |
| PHED | Pesticide Handler Exposure Database |
| RfD | Reference Dose |
| RfD | Reference Dose |
| RQ | Risk Quotient |
| RUD | Residue Unit Dose |
| TW | Tested Species Weight |
| UF | Uncertainty Factor |
| v/v | Volume per Volume |